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UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

BARBARA STROUGO, Individually and on Behalf of All Others Similarly Situated, Plaintiff, vs. MALLINCKRODT PUBLIC LIMITED COMPANY, et al., Defendants.	Civil Action No. 20-10100(AET)(TJB) **AMENDED COMPLAINT and DEMAND FOR JURY TRIAL**

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Lead plaintiff Canadian Elevator Industry Pension Trust Fund ("Lead Plaintiff" or "Plaintiff"), on behalf of itself and all other persons similarly situated, by Plaintiff's undersigned attorneys, for Plaintiff's amended complaint for violations of the federal securities laws against Defendants (defined below), alleges the following based upon personal knowledge as to Plaintiff and Plaintiff's own acts, and upon information and belief as to all other matters based on the investigation conducted by and through Plaintiff's attorneys, which included, among other things, the review and analysis of: (i) Securities Exchange Commission ("SEC") filings made by Mallinckrodt plc ("Mallinckrodt" or the "Company"); (ii) press releases, public statements, public letters, and other publications disseminated by, or concerning, Defendants; (iii) the allegations and facts contained in documents filed in *Mallinckrodt ARD LLC v. Verma, et al.*, No. 1:19-cv-01471-TFH (D.D.C.) (the "CMS Litigation"); (iv) the allegations and facts contained in documents filed in *Mallinckrodt ARD LLC v. Verma, et al.*, No. 20-5154 (D.C. Cir.) (the "CMS Litigation Appeal"); (v) the allegations and facts contained in documents filed in *Landolt v. Mallinckrodt ARD LLC*, No. 1:18-cv-11931-PBS (D. Mass.) ("*Landolt*"); (vi) the allegations and facts contained in documents filed in *U.S. ex rel. Strunck v. Mallinckrodt ARD LLC*, No. 2:12-cv-0175-BMS (E.D. Pa.) ("*Strunck*"); (vii) the allegations and facts contained in documents filed in *U.S. ex rel. Clark v. Mallinckrodt ARD LLC*, No. 2:13-cv-1776-BMS (E.D. Pa.); (viii) transcripts of investor conference calls with Mallinckrodt senior management; (ix) information posted on Mallinckrodt's corporate website; (x) securities analyst reports concerning Mallinckrodt; (xi) news articles and media coverage concerning the events detailed herein; and (xii) drug labels, approval information, and other materials made publicly available by the U.S. Food and Drug Administration ("FDA").

The investigation of Plaintiff's attorneys is continuing, yet certain additional facts supporting these allegations are known only to Defendants or are exclusively within their custody or control.[1] Plaintiff believes that substantial evidentiary support will exist for the allegations set forth herein after a reasonable opportunity for discovery.

NATURE OF THE ACTION

1. This is a federal securities class action on behalf of all purchasers of the common stock of Mallinckrodt between May 3, 2016 and March 18, 2020, inclusive (the "Class Period"). Plaintiff asserts claims against Mallinckrodt and certain of its senior executives and/or directors under §§10(b) and 20(a) of the Securities Exchange Act of 1934 (the "Exchange Act") and SEC Rule l0b-5 promulgated thereunder (17 C.F.R. §240.10b-5), as amended by the Private Securities Litigation Reform Act of 1995 ("PSLRA").

2. Mallinckrodt is a pharmaceutical company whose most important drug during the Class Period was H.P. Acthar Gel ("Acthar"). Specifically, Acthar was Mallinckrodt's single highest selling product during the Class Period, consistently representing at least one-third of the Company's total annual net sales.

3. This class action stems from Defendants' materially false and misleading statements and omissions concerning the rebates Mallinckrodt owed to the government for Acthar sales to Medicaid patients, the amount of which is calculated using the base date average manufacturer's price ("AMP"). During the Class Period, Defendants knew, or recklessly disregarded, that the Centers for Medicare and Medicaid Services ("CMS") had repeatedly informed Mallinckrodt that it was knowingly using the wrong base date AMP for calculating the Medicaid rebate the Company owed CMS each quarter since

[1] Lead Plaintiff's attorneys have made Freedom of Information Act ("FOIA") requests to the FDA, SEC, Department of Justice ("DOJ"), and CMS (defined below) for documents relating to Plaintiff's allegations. If these FOIA requests result in information that support Plaintiff's allegations, or broaden the scope of this complaint, Plaintiff intends to amend this complaint pursuant to Federal Rule of Civil Procedure 15(a) within a reasonable period of time.

Mallinckrodt acquired Acthar from Questcor in August 2014.[2]

4. By way of background, Mallinckrodt, and Questcor before it, engaged in brazen price gouging of Acthar that has made Acthar one of the most overpriced drugs in the United States. When Acthar received FDA approval in 1952, it was sold for less than $40 per 5 ml dose. Acthar stayed roughly the same price until 2001, when it was acquired by Questcor and the price began to rapidly rise. Those price increases continued under Mallinckrodt's ownership, and a 5 ml dose of Acthar now retails for over $40,000, an over 1,000 times price increase in less than 20 years.

5. To participate in the Medicaid Drug Rebate Program ("MDRP") that is overseen by CMS, which substantially defrays the expense of costly drugs like Acthar for patients who qualify for Medicaid, drug manufacturers like Mallinckrodt are obligated to pay the government rebates on drug sales in order to protect Medicaid from drug price increases that outpace the rate of inflation.

6. Seeking to avoid compensating the government for the rebates Congress mandated that Mallinckrodt must pay to guard against usurious drug price increases, Defendants knowingly, or recklessly, used the incorrect base date AMP for calculating the rebate owed for Acthar. This scheme allowed Mallinckrodt to avoid paying over $600 million in rebates by the end of the Class Period. Instead of being used to defray Medicaid costs, these illegally avoided rebates falsely and artificially boosted Mallinckrodt's sales and profits in violation of well-established accounting principles.

7. CMS informed Mallinckrodt numerous times during the Class Period that the Company was using the wrong base date AMP for Acthar, specifically including defendant Schaefer, Mallinckrodt's Corporate Controller and Principle Accounting Officer ("PAO"), and defendant Casey, Mallinckrodt's General Counsel, in these communications. By April 2016, just before the start of the Class Period, Mallinckrodt's own regulatory department recognized that CMS's position was correct

[2] Capitalized terms used in this section are defined later in this Complaint.

and that Mallinckrodt was knowingly using the wrong base date AMP for Acthar.

8. Internally, Mallinckrodt calculated that its failure to properly comply with its obligations under the MDRP caused a liability of hundreds of millions of dollars, which was deemed "significantly material." Indeed, throughout 2018, defendant Schaefer repeatedly informed the Audit Committee of the Board , which included defendants Reed, Russell, Booth, and Carter, that CMS believed that Mallinckrodt was using the wrong base date AMP for Acthar and that complying with CMS would cost the Company "hundreds of millions of dollars."

9. Not only was this liability calculated by Mallinckrodt to be hundreds of millions of dollars, Mallinckrodt also understood that if it had to use the correct base date AMP for Acthar, net sales of Acthar would be reduced by approximately 10% on a yearly basis going forward in perpetuity because the proper rebate would have to be remitted to CMS.

10. By virtue of this unlawful scheme to avoid paying the rebates owed to CMS for Acthar sales, Defendants knowingly or recklessly caused Mallinckrodt to issue, in violation of GAAP, the Class Period Financial Statements, which: (i) materially inflated Mallinckrodt's reported net sales and understated its reported accrued liabilities, which resulted in a concomitant inflation in Mallinckrodt's reported net income; and (ii) misrepresented contingent liabilities associated with the rebates owed to CMS for Acthar.

11. Defendants' knowing, or reckless, failure to comply with CMS's repeated requests before and during the Class Period to use the correct base date AMP for Acthar also rendered false the Company's FY19 guidance for Acthar net sales, which Defendants repeatedly claimed would be in excess of $1 billion. In reality, Defendants knew, or recklessly disregarded, during the Class Period that the reduction to Acthar's FY19 net sales caused by using the correct base date AMP for Acthar would cause Acthar net sales to fall well below $1 billion.

12. Defendants also made a host of false and misleading omissions in the Company's Class

Period Forms 10-K and 10-Q in describing risk factors for Acthar and Mallinckrodt's exposure to the MDRP. At no point during the Class Period did Defendants provide investors with any indication that CMS had informed the Company that Mallinckrodt was using the wrong base date AMP for Acthar and, as a result, owed hundreds of millions of dollars in rebates to the government.

13. In addition, Defendants repeatedly touted Mallinckrodt's efforts during the Class Period to develop clinical trial data supporting the use of Acthar in diseases and indications that Acthar has not previously been used to treat. Defendants, however, failed to disclose that these efforts were being undertaken to give the impression that alternative revenue opportunities existed for Acthar, which would offset the expected 10% decline in net sales of Acthar as a result of the increased rebates that Mallinckrodt now had to pay.

14. Separate from the issues regarding CMS, the 2018 Form 10-K was also materially misleading because it failed to disclose that the Company was negotiating at that time with the DOJ and two whistleblowers to resolve litigation stemming from the Company's alleged illegal promotional efforts for Acthar, *i.e.*, the *Strunck* litigation.

15. For all the foregoing reasons, in addition to making numerous materially false and misleading statements and omissions, Defendants repeatedly violated Items 103, 303, and 503 of Regulation S-K, which required Mallinckrodt to disclose legal proceedings, known trends, events, and uncertainties, and material risks in its Class Period Forms 10-K and 10-Q.

16. Investors learned about Defendants' materially misleading statements and omissions through a series of disclosures.

17. First, on April 30, 2019, a *CNN* article was published during the trading day that disclosed the existence of the *Strunck* litigation for the first time.

18. Next, on May 21, 2019, the Company announced the filing of the CMS Litigation, which is the first time that investors learned that CMS was requiring the Company to repay hundreds of

millions of dollars for illegally avoiding Acthar rebates.

19. Then, on August 6, 2019, investors learned for the first time that Mallinckrodt could not achieve the Acthar FY19 Guidance because future annual Acthar net sales would be depressed by approximately 10% if the Company began using the correct base date AMP for Acthar.

20. Next, on March 3, 2020, investors learned for the first time about the existence of *Landolt*, a whistleblower lawsuit brought by a former Mallinckrodt executive and direct report to defendant Schaefer, and that the government was intervening in *Landolt*.

21. Finally, on March 16, 2020, through the dismissal of the CMS Litigation, investors first learned that Defendants lacked any reasonable basis for withholding Acthar rebates at any point during the Class Period.

22. Mallinckrodt's stock dropped precipitously on each occasion, causing damage to Plaintiff and the Proposed Class.

JURISDICTION AND VENUE

23. Jurisdiction is conferred by §27 of the Exchange Act. The claims asserted herein arise under §§10(b) and 20(a) of the Exchange Act [15 U.S.C. §§78j(b) and 78t(a)] and Rule 10b-5.

24. This Court has jurisdiction over the subject matter of this action under 28 U.S.C. §1331 and §27 of the Exchange Act.

25. Venue is proper in this District pursuant to §27 of the Exchange Act and 28 U.S.C. §1391(b).

26. Dissemination of materially false and misleading information by Defendants occurred in this District.

27. In addition, the principal office for Mallinckrodt's Specialty Brands business, which includes Acthar, was located in Bedminster Township, New Jersey, during the Class Period.

28. In connection with the acts alleged herein, Defendants, directly or indirectly, used the

means and instrumentalities of interstate commerce, including, but not limited to, the mails, telephonic communications, and the facilities of the national securities markets.

PARTIES

29. Lead Plaintiff Canadian Elevator Industry Pension Trust Fund purchased Mallinckrodt common stock during the Class Period, as set forth in the attached certification, which is incorporated by reference herein, and was damaged thereby.

30. Defendant Mallinckrodt is a pharmaceutical company that licenses, clinically develops, markets, and sells pharmaceutical drugs principally in the United States, including in New York. Mallinckrodt's common stock is traded on the New York Stock Exchange ("NYSE") under the symbol "MNK." According to Mallinckrodt's Form 10-K for the fiscal year ended December 31, 2018 ("FY18"), which was filed with the SEC on February 26, 2019 (the "2018 Form 10-K"), the Company had 83,505,008 shares of common stock outstanding as of February 22, 2019.

31. Defendant Mark C. Trudeau ("Trudeau") has served as the Company's President, Chief Executive Officer ("CEO"), and a director on Mallinckrodt's board of directors (the "Board") since June 2013. Defendant Trudeau is listed as one of the six members of Mallinckrodt's executive committee (the "Executive Committee") on Mallinckrodt's corporate website. According to the Form DEF14A filed by Mallinckrodt with the SEC on April 4, 2018, defendant Trudeau has been an executive officer of Mallinckrodt during his tenure as CEO. Defendant Trudeau signed each of the Company's Forms 10-K and Forms 10-Q filed with the SEC during the Class Period. Defendant Trudeau spoke at numerous Mallinckrodt investor conferences during the Class Period.

32. Defendant Matthew K. Harbaugh ("Harbaugh") served as the Company's Executive Vice President and Chief Financial Officer ("CFO") from 2013 until December 2018. In May 2018, defendant Harbaugh also became President of Mallinckrodt's Specialty Generics business. In December 2018, defendant Harbaugh stepped down as the Company's CFO but retained his oversight

of Mallinckrodt's Specialty Generics business. Defendant Harbaugh resigned as President of Mallinckrodt's Specialty Generics business on September 6, 2019. During his tenure, Defendant Harbaugh was one of the members of Mallinckrodt's Executive Committee. Defendant Harbaugh signed several of the Company's Forms 10-K and 10-Q, all of which were filed during the Class Period. Defendant Harbaugh spoke at Mallinckrodt investor conferences during the Class Period.

33. Defendant George A. Kegler ("Kegler") served as the Company's interim CFO from December 2018 until defendant Reasons was hired on March 18, 2019. Defendant Kegler had previously served as the Vice President of Finance at Mallinckrodt beginning in 2013. Defendant Kegler was an executive officer of Mallinckrodt during his tenure as CFO. Defendant Kegler left Mallinckrodt in March 2019. Defendant Kegler signed the 2018 Form 10-K, which was filed during the Class Period. Defendant Kegler spoke at a Mallinckrodt investor conference during the Class Period.

34. Defendant Bryan M. Reasons ("Reasons") has served as the Company's Executive Vice President and CFO since March 18, 2019. Defendant Reasons is listed as one of the six members of Mallinckrodt's Executive Committee. Defendant Reasons signed all of Mallinckrodt's Forms 10-Q starting with the 1Q19 Form 10-Q and the 2019 Form 10-K, which was filed during the Class Period. Defendant Reasons spoke at Mallinckrodt investor conferences during the Class Period.

35. Defendant Kathleen A. Schaefer ("Schaefer") has served as the Company's Senior Vice President and Corporate Controller since December 2013. Defendant Schaefer is listed as one of the six senior leaders of Mallinckrodt on the Company's corporate website. According to each of the Company's Forms 10-K filed during the Class Period, defendant Schaefer was the PAO of Mallinckrodt during the Class Period. Defendant Schaefer signed each of the Company's Forms 10-K filed with the SEC during the Class Period.

36. Defendant Angus C. Russell ("Russell") has served as a director on the Board since

August 2014 and as Chairman of the Board since May 2018. Defendant Russell was a member of the Audit Committee during the Class Period. Defendant Russell signed each of the Company's Forms 10-K filed with the SEC during the Class Period.

37. Defendant Melvin D. Booth ("Booth") served as a director on the Board and as Chairman of the Board from March 2013 until May 2018. From the beginning of the Class Period until May 16, 2018, defendant Booth was a member of the Audit Committee. Defendant Booth signed the 2016 and 2017 Forms 10-K (both defined below), which were filed with the SEC during the Class Period.

38. Defendant JoAnn A. Reed ("Reed") has served as a director on the Board since June 2013. Defendant Reed was the Chairwoman of the Audit Committee during the Class Period. According to the Board, defendant Reed was "an audit committee financial expert" during the Class Period. Defendant Reed signed each of the Company's Forms 10-K filed with the SEC during the Class Period.

39. Defendant Paul R. Carter ("Carter") has served as a director on the Board since May 2018. Upon his election to the Board, defendant Carter became a member of the Audit Committee in May 2018 and remained a member for the rest of the Class Period. Defendant Carter signed the 2018 Form 10-K, which was filed with the SEC during the Class Period.

40. Defendant Mark J. Casey ("Casey") has served as Executive Vice President and Chief Legal Officer ("CLO") of Mallinckrodt since February 1, 2018. Along with defendants Trudeau and Reasons, defendant Casey is listed as one of the six members of Mallinckrodt's Executive Committee. Defendant Casey signed the Company's March 13, 2019 Form S-8 proxy statement (the "March 2019 Proxy Statement"), which was filed during the Class Period.

41. Defendants Trudeau, Reasons, Harbaugh, Kegler, Schaefer, Russell, Booth, Reed, Carter, and Casey are collectively referred to herein as the "Individual Defendants."

42. Mallinckrodt and the Individual Defendants are collectively referred to herein as "Defendants."

43. Because of the Individual Defendants' positions with the Company, they had access to the adverse undisclosed information about its business, operations, products, operational trends, financial statements, markets and present and future business prospects via internal corporate documents (including the Company's operating plans, budgets and forecasts, and reports of actual operations compared thereto), conversations and connections with other corporate officers and employees, attendance at management and/or Board meetings and committees thereof and via reports and other information provided to them in connection therewith.

44. It is appropriate to treat Defendants as a group for pleading purposes and to presume that the false, misleading, and incomplete information conveyed in the Company's public filings, press releases, and other publications as alleged herein are the collective actions of the narrowly defined group of Defendants identified in ¶¶31-40 above. Each of the above officers and directors of Mallinckrodt, by virtue of their high-level positions with the Company, directly participated in the management of the Company, was directly involved in the day-to-day operations of the Company at the highest levels, and/or was privy to confidential proprietary information concerning the Company and its business, operations, products, growth, financial statements, and financial condition, as alleged herein. The Individual Defendants were involved in drafting, producing, reviewing, and/or disseminating the false and misleading statements and information alleged herein, were aware, or recklessly disregarded, that the false and misleading statements were being issued regarding the Company, and approved or ratified these statements, in violation of the federal securities laws.

45. As officers, directors, and controlling persons of a publicly-held company whose common stock was registered with the SEC pursuant to the Exchange Act and traded on the NYSE, and which is governed by the provisions of the federal securities laws, the Individual Defendants each had a

duty to promptly disseminate accurate and truthful information with respect to the Company's financial condition and performance, growth, operations, financial statements, business, products, markets, management, earnings, and present and future business prospects, and to correct any previously-issued statements that had become materially misleading or untrue, so that the market price of the Company's publicly-traded stock would be based upon truthful and accurate information. Defendants' false and misleading misrepresentations and omissions during the Class Period violated these specific requirements and obligations.

46. The Individual Defendants participated in the drafting, preparation, and/or approval of the various public and shareholder and investor reports and other communications complained of herein and were aware of, or recklessly disregarded, the misstatements contained therein and omissions therefrom, and were aware of their materially false and misleading nature. Because of their executive and managerial positions and/or Board membership with Mallinckrodt, the Individual Defendants each had access to the adverse undisclosed information about Mallinckrodt's business prospects and financial condition and performance as particularized herein and knew (or recklessly disregarded) that these adverse facts rendered the positive representations made by or about Mallinckrodt and its business materially false and misleading.

47. The Individual Defendants, because of their positions of control and authority as officers and/or directors of the Company, were able to and did control the content of the various SEC filings, press releases, and other public statements pertaining to the Company during the Class Period. Each Individual Defendant was provided with copies of the documents alleged herein to be misleading before or shortly after their issuance and/or had the ability and/or opportunity to prevent their issuance or cause them to be corrected. Accordingly, each Individual Defendant is responsible for the accuracy of the public statements detailed herein and is, therefore, primarily liable for the representations contained herein.

48. Each Defendant is liable as a participant in a fraudulent scheme and course of conduct that operated as a fraud or deceit on purchasers of Mallinckrodt common stock by disseminating materially false and misleading statements and/or concealing material adverse facts. The scheme: (i) deceived the investing public regarding Mallinckrodt's financial reporting, business, operations and management, and the intrinsic value of Mallinckrodt's common stock; and (ii) caused Plaintiff and the Class to purchase Mallinckrodt's publicly-traded stock at artificially inflated prices.

FORMER MALLINCKRODT EMPLOYEES CITED HEREIN

49. The Complaint references several former Mallinckrodt employees that have either brought a *qui tam* action against the Company for allegedly violating the False Claims Act and/or provided testimony to the government in the course of its investigation into these *qui tam* allegations. Each witness supports an inference that Defendants knew, or recklessly disregarded, that Mallinckrodt was using the wrong base date AMP for Acthar during the Class Period and that this resulted in Mallinckrodt owing the government hundreds of millions of dollars, as detailed herein. A description of the accounts provided by these witnesses is detailed below, and these accounts are discussed further herein.

(a) James Landolt ("Landolt") was Mallinckrodt's Director of Internal Controls, Gross to New Accounting, and Government Reporting until his resignation from the Company in early July 2017. Landolt reported directly to defendant Schaefer during his tenure as Mallinckrodt's Director of Internal Controls. On September 20, 2018, Landolt brought a *qui tam* lawsuit against Mallinckrodt alleging, *inter alia*, that ever since Mallinckrodt acquired Acthar from Questcor in August 2014, the Company has "knowingly paid the [MDRP] less than it owes in rebates for Acthar and instead retained and used for its benefit funds that belong to the Government."

(b) Kay Forshee ("Forshee") was formerly Mallinckrodt's Senior Manager of Government Reporting who was responsible for overseeing Mallinckrodt's Medicaid drug price

reporting. Forshee provided testimony in the DOJ's investigation into the allegations made by Landolt. Among other things, Forshee testified that Mallinckrodt understood internally by June 2016 that CMS was "requesting that we change the baseline AMP to the original baseline AMP." Further, Forshee testified that she shared with defendant Schaefer in June 2016 the amount of liability that Mallinckrodt would face once it began using the correct base date AMP for Acthar and remitted the rebates the Company owed to the government, which both agreed "was significantly material, the dollar amount."

(c) Misi Daley ("Daley") was formerly an analyst in Mallinckrodt's government reporting group. Daley provided testimony in the DOJ's investigation into the allegations made by Landolt. Among other things, Daley testified that "[Mallinckrodt's r]egulatory [department] agreed with CMS" in April 2016 that Mallinckrodt was using the wrong base date AMP for Acthar.

SUBSTANTIVE ALLEGATIONS

Mallinckrodt and Its Business

50. According to the Company's Form 10-K for the fiscal year ended September 30, 2016 ("FY16"), which was filed on November 29, 2016 (the "2016 Form 10-K"), Mallinckrodt is divided into two businesses: (i) Specialty Brands; and (ii) Specialty Generics. Plaintiff's allegations pertain to the Specialty Brands business, which counts Acthar among its products.

51. Mallinckrodt is headquartered in the United Kingdom and is incorporated under Irish law. Nonetheless, Mallinckrodt's commercial headquarters for its Specialty Brands business is located in Bedminster, New Jersey, its commercial headquarters for its Specialty Generics business is located in Webster Groves, Missouri, and its corporate shared services office is located in Hazelwood, Missouri.

52. Mallinckrodt's Specialty Brands business markets branded pharmaceutical products for autoimmune and rare diseases in the specialty areas of neurology, rheumatology, nephrology, ophthalmology, among other areas.

53. Mallinckrodt's Specialty Generics business markets drugs that include a variety of product formulations containing hydrocodone, oxycodone, and several other controlled substances. Through its Specialty Generics business, Mallinckrodt has long been among the world's largest manufacturers of opioids. Mallinckrodt is currently a defendant in numerous state, municipal, and private litigations targeting the opioid epidemic allegedly caused by companies like Mallinckrodt.

54. According to the 2016 Form 10-K, Specialty Brands accounted for approximately $1.622 billion in net sales during fiscal year 2015 ("FY15"), or approximately 55.5% of Mallinckrodt's total net sales for FY15. Specialty Brands accounted for approximately $2.301 billion in net sales during FY16, or approximately 68% of Mallinckrodt's total net sales for FY16.

55. According to the 2018 Form 10-K, Specialty Brands accounted for approximately $2.35 billion in net sales during the fiscal year ended December 31, 2017 ("FY17"), or approximately 73% of Mallinckrodt's total net sales for FY17. Specialty Brands accounted for approximately $2.31 billion in net sales during FY18, or approximately 72% of Mallinckrodt's total net sales for FY18. Specialty Generics comprised the remainder of Mallinckrodt's FY15, FY16, FY17 and FY18 net sales.

56. According to the 2016 Form 10-K, the majority of Mallinckrodt's FY15 and FY16 net sales for Specialty Brands were made in the United States. Specifically, approximately 99.3% of the $1.622 billion in FY15 net sales for Specialty Brands were made in the United States. Approximately 96.7% of the $2.301 billion in FY16 net sales for Specialty Brands were made in the United States.

57. According to the 2018 Form 10-K, approximately 94% of the $2.35 billion in FY17 net sales for Specialty Brands were made in the United States. Approximately 93% of the $2.31 billion in FY18 net sales for Specialty Brands were made in the United States.

Acthar Was Mallinckrodt's Most Important Drug During the Class Period

58. According to the Company's Form 10-K for FY17, which was filed after market close on February 27, 2018 (the "2017 Form 10-K"), Acthar is an injectable drug approved by the FDA for

use in 19 indications, but which generates substantially all of its sales from nine indications on its label, including: (i) treating infantile spasms; (ii) treating acute exacerbations of multiple sclerosis ("MS") in adults; (iii) as an adjunctive therapy for short-term administration in various rheumatic disorders; (iv) during an exacerbation or as maintenance therapy in cases of lupus or systemic dermatomyositis; (v) for severe erythema multiforme or Stevens-Johnson syndrome; (vi) for serum sickness; (vii) for severe acute and chronic allergic and inflammatory processes involving the eye and its adnexa; (viii) for systemic sarcoidosis; and (ix) to induce a remission in nephrotic syndrome.

59. Acthar is a dangerous drug with wide-ranging and potentially life threatening adverse effects. Thus, its FDA-approved label specifically warns of fourteen serious adverse side effects that may occur in Acthar users.

60. Acthar was Mallinckrodt's most important drug during the Class Period. According to the 2016 Form 10-K, Acthar net sales in FY15 were $1.037 billion. This amount constitutes approximately 64% of Specialty Brands' net sales for FY15 and approximately 35% of Mallinckrodt's total net sales in FY15. Thus, Acthar was the single largest contributor to Mallinckrodt's net sales during FY15.

61. According to the 2016 Form 10-K, Acthar net sales in FY16 were $1.160 billion. This amount constitutes approximately 50% of Specialty Brands' net sales for FY16 and approximately 34% of Mallinckrodt's total net sales in FY16. Thus, Acthar was the single largest contributor to Mallinckrodt's net sales during FY16.

62. According to the 2018 Form 10-K, Acthar net sales in FY17 were $1.195 billion. This amount constitutes approximately 51% of Specialty Brands' net sales for FY17 and approximately 37% of Mallinckrodt's total net sales in FY17. Thus, Acthar was the single largest contributor to Mallinckrodt's net sales during FY17.

63. Likewise, according to the 2018 Form 10-K, Acthar net sales in FY18 were $1.110

billion. This amount constitutes approximately 48% of Specialty Brands' net sales for FY18 and approximately 35% of Mallinckrodt's total net sales in FY18. Thus, Acthar was the single largest contributor to Mallinckrodt's net sales during FY18.

64. Defendants repeatedly attested to the importance of Acthar to Mallinckrodt's business and operations during the Class Period. For example, during an investor conference presentation on March 5, 2018, defendant Trudeau stated that "a big part of [Mallinckrodt's] story is Acthar[.]" Likewise, an analyst commented during an investor conference presentation for Mallinckrodt on March 14, 2018, that it is "almost impossible to talk about Mallinckrodt without bringing up the subject of Acthar." Indeed, substantial portions of the investor conferences held by Mallinckrodt during the Class Period saw numerous questions posed by analysts about Acthar, to which Defendants routinely provided substantive responses.

The Fallout From Mallinckrodt's Efforts to Price Gouge Acthar

65. Acthar is naturally derived from the pituitary glands of pigs. It was discovered in 1949 by Armour & Company ("Armour"), a Chicago meatpacker, who sought to find economical uses for the byproducts of slaughtered pigs. In 1952, Armour submitted a new drug application ("NDA") for Acthar and received FDA approval for Acthar to treat approximately 50 diseases. The NDA issued for Acthar in 1952 remains the NDA that the FDA assigns to Acthar today.

66. In 1952, the FDA did not require companies to have new drugs undergo the rigorous clinical trial testing that is required today to demonstrate efficacy. Thus, the FDA approved Acthar without requiring it to undergo efficacy testing and the drug is grandfathered in by the FDA.

67. By 2001, Acthar was owned by Aventis Pharmaceuticals Inc. and retailed for $40 per 5 ml vial, which is the standard dosage. Acthar was purchased that year by Questcor Pharmaceuticals, Inc. ("Questcor"), for $100,000 plus a 1% royalty on annual sales over $10 million.

68. Upon purchasing Acthar, Questcor immediately raised its price to $700 per 5 ml vial.

By 2006, annual sales of Acthar were approximately $12 million, at which time it was being sold for approximately $1,650 per 5 ml vial.

69. In June 2006, Questcor submitted a supplemental New Drug Application ("sNDA") to the FDA seeking approval to market Acthar for the treatment of infantile spasms, which was not one of the treatments included in Acthar's original FDA approval in 1952.

70. In anticipation of obtaining FDA approval for Acthar to treat infantile spasms, Questcor increased the cost of Acthar in August 2007 to an astonishing $23,000 per 5 ml vial.

71. In October 2010, the FDA approved the sNDA and allowed Questcor to add infantile spasms to Acthar's label. The FDA also granted Acthar orphan drug status for treating infantile spasms, meaning that Questcor would have seven years of marketing exclusively for treating infantile spasms.

72. By 2011, Acthar was retailing for $24,195 per 5 ml vial.

73. By 2012, Acthar was retailing for over $28,000 per 5 ml vial.

74. On April 7, 2014, defendant Trudeau announced that Mallinckrodt was acquiring Questcor for $5.6 billion. According to Questcor's Form 10-K for fiscal year 2013 ("FY13"), filed on February 26, 2014 – the last Form 10-K Questcor filed before the merger – Acthar sales in FY13 were $761.3 million, or 92.2%, of the $825.7 million in sales made by Questcor in FY13. Thus, Acthar comprised substantially all of Questcor's sales when Mallinckrodt purchased Questcor.

75. Mallinckrodt's acquisition of Questcor closed on August 14, 2014.

76. Starting in August 2014, Mallinckrodt began aggressively marketing Acthar and continued to substantially increase its price. As reflected above in ¶¶60-63, at no point during the Class Period did Acthar achieve annual net sales for Mallinckrodt of less than $1 billion.

77. By 2017, Mallinckrodt had raised the price of Acthar to over $34,000 per 5 ml vial. At this point, public backlash against Mallinckrodt was growing as the astronomical sums that Acthar was

costing government and private payers became publicly known. For example, according to *The New York Times*, total Medicare spending on Acthar was $504 million in 2015, up from $49.5 million in 2011.

78. According to the Medicare Drug Spending Dashboard, Acthar was the single most expensive drug, per patient, for which the government paid during 2015. Of the 3,100 government beneficiaries using Acthar during 2015, Medicare spent an average of $162,371 per beneficiary.

79. In addition, in July 2016, United HealthCare, then the largest private payer of prescription drugs in the United States, determined that Acthar was more expensive than alternatives that were likely to produce equivalent results. United HealthCare determined that Acthar "is unproven and not medically necessary" for all but three of its label indications.

80. Starting in 2017, payers of prescription drugs, most notably Medicare and Medicaid, began to push back against Mallinckrodt for grossly inflating the price of Acthar. For example, on May 19, 2017, Express Scripts Senior Vice President Everett Neville stated that "[Acthar] is a pretty poor drug with a very limited need" and that "I personally told [Mallinckrodt's] management team that their drug is hugely overpriced."

81. On November 7, 2017, defendants Trudeau and Harbaugh admitted that Acthar sales were being negatively impacted because, among other things, payers were beginning to not reimburse Mallinckrodt for Acthar prescriptions due to its excessive price.

82. Nonetheless, Mallinckrodt continued to increase Acthar's price, with a 5 ml vial priced at $40,612.75 as of July 10, 2019.

The Medicaid Drug Rebate Program

83. Medicaid is a program jointly run by the federal and state governments that, among other things, provides prescription drug coverage primarily for economically and physically challenged Americans.

84. The federal government pays approximately 50% of Medicaid's share of prescription drug costs. The remaining 50% is divided between state and local authorities. In order to obtain state Medicaid coverage, CMS requires manufacturers, like Mallinckrodt and Questcor, to join the MDRP. Congress enacted the MDRP to ensure that Medicaid does not pay more for prescription drugs than private payers. *See* H.R. Rep. No. 101-881 (1990).

85. Mallinckrodt signed up for the MDRP in 1991, and re-enrolled in 2007 and in 2018. Questcor signed up for the MDRP in 2007.

86. Participating in the MDRP requires manufacturers to pay the states a rebate for the manufacturers' drugs that are covered by a state's Medicaid plan, such as Acthar, in return for Medicaid guaranteeing coverage for the drugs. The rebates are then shared with the federal government.

87. Manufacturers are responsible for submitting, among other things, accurate pricing data, including the base date AMP for a particular drug, to CMS on a quarterly basis so that CMS and the states can calculate the rebates owed by the manufacturer for a particular drug. *See generally* 42 U.S.C. § 1396r-8.

88. Manufacturers are responsible for paying the proper rebates on a quarterly basis to the government. The amount received by a state Medicaid program in rebates reduces the total amount expended under that state's Medicaid plan. The less that a state receives in rebates means the more that the federal government must pay to each state.[3]

89. The rebate consists of two components: (i) the basic rebate; and (ii) an additional rebate. The central component for calculating each rebate is the drug's base date average manufacturer price. *See* 42 C.F.R. § 447.504. Once it is set, the base date AMP is generally used across the life of the

[3] *See* https://www.medicaid.gov/medicaid/prescription-drugs/medicaid-drug-rebate-program/index.html (last visited August 10, 2020).

drug.

90. The additional rebate is calculated by subtracting the base date AMP from the current quarter AMP for a drug. The base date AMP is the inflation-adjusted AMP of a drug that is intended to rebate the amount that a manufacturer has increased its drug prices beyond the amount necessary to account for inflation. *See* 42 C.F.R. § 447.509.

91. If the drug was approved by the FDA and marketed by July 1, 1990, like Acthar was, the additional rebate is calculated by: (i) adjusting the drug's 1990 AMP for inflation since that time; (ii) comparing the drug's inflation-adjusted 1990 AMP to the drug's actual current AMP; and (iii) if the current AMP is higher than the inflation-adjusted 1990 AMP, paying the difference for each unit that a state Medicaid program purchased. *See* 42 U.S.C. § 1396r-8(c)(2)(A).

92. If the drug was approved by the FDA and first marketed after July 1, 1990, the same formula applies, but it uses the first full quarter after the drug was first marketed rather than the third quarter of 1990 as the basis for determining the additional rebate. *See* 42 U.S.C. § 1396r-8(c)(2)(B).

93. Thus, the date upon which the FDA approves a drug for sale and marketing is critical in determining the base date AMP for that drug.

94. If manufacturers increase the price of a drug much faster than the rate of inflation, as Mallinckrodt and Questcor did with Acthar, the "additional rebate" owed for that drug can be substantial. To mitigate against the rebate being an onerous burden on manufacturers, the MDRP limits the total rebate owed to no more than 100% of the drug's AMP.

95. To use the example provided by Mallinckrodt in the CMS Litigation, if a drug's base date AMP is $100 and the inflation-adjusted base date AMP is $110, and the drug's AMP for the reporting quarter is $120, the drug's price increase has outpaced inflation and the manufacturer owes an additional rebate of $10 ($120 minus $110).

96. Essentially, the lower the base date AMP, the higher the rebate manufacturers must pay

the government. Raising the base date AMP for a drug can reduce a manufacturers' rebate burden significantly.

Questcor Fraudulently Obtained A New Base Date AMP For Acthar in 2013

97. Drug manufacturers must file an NDA with the FDA to obtain approval for a new drug to be sold and marketed in the United States.

98. When a manufacturer submits an NDA for a drug, the FDA assigns the drug a unique six-digit NDA number. If the drug is approved, that NDA number is assigned to the drug for its entire lifetime.

99. Nonetheless, the FDA allows manufacturers to submit sNDAs to change a drug's label to, for example, add a new indication that the drug can treat that was not covered by the NDA. *See* 21 C.F.R. §§ 314.70-71; 21 C.F.R. § 314.3(b). However, a drug retains the same six-digit NDA number even when an sNDA has been approved to add an indication to a drug's label. Before July 27, 2009, if the sNDA required review by an FDA division other than the one that approved the original NDA, the FDA assigned the sNDA an administrative "Type 6 NDA" that provided a new temporary NDA tracking number. Because the Type 6 NDA only had an internal administrative function within the FDA, the FDA closed the temporary Type 6 NDAs if the sNDA received approval. The original NDA would then continue to be associated with the drug for its new and old indications.[4]

100. Before and during the Class Period, Defendants knew, or recklessly disregarded, that Mallinckrodt was intentionally using the wrong base date AMP for Acthar to illegally avoid paying hundreds of millions of dollars in rebates to the government.

101. Defendants further understood during the Class Period that the government was demanding the return of over $600 million and that using the correct base date AMP for Acthar would mean that Acthar net sales going forward would decline by approximately 10% due to the higher,

[4] *See* https://www.fda.gov/media/94381/download (last visited August 10, 2020).

correct rebates that would now have to be paid to the government.

102. The NDA number that Armour received for Acthar in 1952 was NDA 008372. This has remained the NDA number associated with Acthar ever since. It remains the NDA number for Acthar today.

103. After Questcor submitted the sNDA in 2006 to obtain an additional indication for Acthar to treat infantile spasms, the FDA subsequently informed Questcor by email on August 8, 2008, that the FDA had "created a separate NDA number for your infantile spasm submission ***for administrative purposes***" (emphasis added), which was NDA 022432. An internal FDA memo dated August 8, 2008, confirmed that the Acthar sNDA was assigned an administrative Type 6 NDA because an FDA division that did not review Acthar's NDA needed to review the sNDA for infantile spasms.

104. When the FDA approved the sNDA for Acthar in 2010, the approval letter directed Questcor to address all future submissions for Acthar, including for the infantile spasms indication, to "the original NDA 008372 for this drug product, not to this NDA [022432]." Questcor was specifically directed in this letter to "not make submissions to this NDA [022432]" "[i]n the future[.]"

105. Thus, the sNDA did not represent the approval of a new drug, just an additional indication for an existing drug that was previously FDA-approved under NDA 008372 in 1952. Questcor recognized this in its May 3, 2011 letter to the FDA, in which Questcor admitted that "[t]he efficacy supplement for Treatment of Infantile Spasms was approved under the tracking NDA number 22,432 on October 15, 2010" and that "since the tracking NDA number [022432] ***will no longer be used***, we are submitting this Changes Being Effected Labeling Supplement ***to the parent NDA 08,372***." (emphasis added).

106. After acquiring Acthar, Mallinckrodt was informed by the FDA by letter on March 24, 2015, that the sNDA number was temporary and that the original NDA for Acthar applied going forward. Specifically, the FDA informed Mallinckrodt that "the indication for the treatment of infantile

spasms [is] to be associated with the parent NDA number 008372, ***since the tracking NDA number 022432 will no longer be used***." (emphasis added). Consistent with the FDA's instructions, Mallinckrodt thereafter has directed supplements to Acthar's label to NDA 008372, not the temporary NDA 022432.

107. Until 2013, Questcor used a 1990 Base Date AMP to calculate the additional rebate owed for Acthar. By 2010, the additional rebate that Questcor owed for Acthar had risen to the maximum total rebate amount, or 100% of Acthar's AMP, each quarter because Questcor had increased the price of Acthar much faster than the rate of inflation.

108. Rather than lower Acthar's price, Questcor petitioned CMS to reset Acthar's base date AMP. Questcor's reasoning for this request was that the sNDA resulted in a new NDA number (022432) being assigned for Acthar – *i.e.*, the temporary Type 6 NDA – meaning that Questcor was presenting Acthar to be an entirely new drug as of 2010.

109. Instead of characterizing the 2010 sNDA approval as adding an indication for Acthar, Questcor instead portrayed the 2010 approval as being one for a new drug entirely so that a 2013 base date could be used for Acthar. Doing so would save Questcor hundreds of millions of dollars in Acthar rebates under the MDRP. Questcor never informed CMS that it knew that NDA 022432 was a temporary administrative number that would no longer be used once the sNDA was approved in 2010 or that the FDA had instructed Questcor that Acthar's original NDA would remain in place.

110. The highest levels of Questcor recognized that its attempt to reset Acthar's base date AMP was unlikely to succeed. An email from Questcor's former CEO, Don Bailey ("Bailey"), to Questcor's former board of directors on May 9, 2012 states that Questcor's attempt to get a new base date AMP for Acthar had a "probability" that "is still low here, but non-zero."

111. Nonetheless, based upon the misrepresentations made by Questcor, CMS approved a new base date AMP for Acthar on August 6, 2012, because "the recently approved Acthar Gel was

approved under a different [NDA] from the original product." CMS included a caveat in its letter, however, that its decision "is limited to and based upon the facts and information presented to [CMS] and has no applicability to a different set of facts even if such facts appear similar in nature or in scope."

112. In January 2013, Questcor reported a new base date AMP for Acthar to CMS. Questcor began paying rebates on Acthar as if it had first marketed the drug in 2013 instead of 1990, despite Acthar's price having increased by a factor of hundreds since 1990.

113. As recognized by Bailey in an August 22, 2012 email to Questcor's former Chief Commercial Officer, Steve Cartt ("Cartt"), the reduction in the additional rebate achieved by obtaining a new base date AMP for Acthar was "over $60M [per year]" and "most of this falls to the op income bottom line." Cartt's response was that "[w]ow, that is stunning."

114. Quickly recognizing that Questcor had duped CMS, on May 28, 2013, a CMS official emailed Questcor's Director of Business Analytics and Evaluation to request that Questcor correct Acthar's base date AMP. The CMS official noted that because Acthar was approved under NDA 008372, the 1990 base date AMP for Acthar needed to be used by Questcor. Questcor failed to comply with this request.

Defendants Knew, or Recklessly Disregarded, That Mallinckrodt Knowingly Used the Wrong AMP Base Date for Acthar to Avoid Hundreds of Millions of Dollars in Rebates

115. By the beginning of the Class Period, Defendants Mallinckrodt, Trudeau, Harbaugh, Kegler, Schaefer, Russell, Booth, and Reed knew about, or recklessly disregarded, Questcor's scheme to defraud CMS in obtaining a new base date AMP for Acthar in 2012 and CMS's effort to get Questcor to revert to the correct base date AMP for Acthar in May 2013. In addition, at all relevant times during the Class Period, Defendants knew, or recklessly disregarded, that Mallinckrodt was illegally paying less in Acthar rebates than required by the MDRP and had amassed a debt to the

government of hundreds of millions of dollars.

116. According to the joint proxy statement that was filed by Mallinckrodt with the SEC on Form 424B3 on July 14, 2014, which was intended to persuade Mallinckrodt's shareholders to vote to approve the Company's acquisition of Questcor (the "2014 Proxy Statement"), on February 27, 2014, the Audit Committee and Mallinckrodt's management met to discuss, among other things, "the due diligence activities and findings that had taken place to date."

117. According to the 2014 Proxy Statement, on March 11, 2014, the Board met with Mallinckrodt's management to again discuss "the due diligence activities and findings that had occurred to date."

118. Likewise, the 2014 Proxy Statement explained that on March 20 and 21, 2014, the Board met with Mallinckrodt's management to again discuss "the due diligence activities and findings that had occurred to date."

119. According to the 2014 Proxy Statement, on April 5, 2014, the Audit Committee met with Mallinckrodt's management and discussed "the results of the extensive due diligence on Questcor that had been conducted to date[.]"

120. Indeed, according to the 2014 Proxy Statement, one of the principal reasons underlying the Board's unanimous decision to recommend that Mallinckrodt's shareholders approve the Company's acquisition of Questcor was "[t]he scope of the due diligence investigation of Questcor conducted by Mallinckrodt management and outside advisors and consultants (which included in-depth reviews of organizational, operational, financial, commercial, regulatory, legal, employee and other matters), and the results of that investigation."

121. In addition, according to defendant Trudeau's remarks in the Form 425 filed by Mallinckrodt on April 7, 2014 (the "Form 425"), which was part of the filings made in connection with the merger of Mallinckrodt and Questcor, Mallinckrodt had conducted "significant due diligence" on

Questcor before the acquisition. Bailey is also quoted in the Form 425 touting the merger.

122. Furthermore, Hugh O'Neill ("O'Neill"), who was the head of Mallinckrodt's Specialty Brands business when Mallinckrodt acquired Questcor in August 2014, emphasized the thoroughness of the due diligence efforts with respect to reimbursements for Acthar. O'Neill is presently Mallinckrodt's Executive Vice President and Chief Commercial Officer, and is a member of the Company's Executive Committee, together with defendants Trudeau, Reasons, and Casey.

123. Specifically, during an investor earnings call on September 8, 2014, O'Neill stated, in pertinent part, as follows:

> So it is important know that when we looked at this we did diligence across the board in multiple facets. So we looked at not only the durability of the product, the manufacturing of the product, the marketing practices of the product, how the product has been accepted at the physician level, how we actually are -- how it has been positioned and so forth.
>
> And to be honest, we thought because there was so much smoke that we would find some fire there. Because when you go into a diligence like this you would expect with all the noise around this asset that there would be more there than not. And I will tell you that when we looked at it across the board from the way the product is manufactured to the way the product is sold ***to the way the product is actually positioned for reimbursement***, all that, that ***we've actually found nothing there that would cause us any concern***.

(emphasis added).

124. Shortly after Mallinckrodt acquired Questcor, CMS requested that Mallinckrodt correct the base date AMP being used for Acthar and return the illegally withheld rebates.

125. According to the complaint filed by Mallinckrodt against CMS in the CMS Litigation (the "CMS Complaint"), comprised of allegations by Mallinckrodt and supported by numerous letters and emails appended as exhibits, on April 13, 2016, CMS sent a letter to Forshee – the former Mallinckrodt Senior Manager of Government Reporting who was responsible for overseeing Mallinckrodt's Medicaid drug price reporting – explaining that the wrong base date AMP was being used for Acthar. Specifically, CMS stated that the NDA assigned for the sNDA (022432) was

temporary and that future submissions were supposed to be directed to the original NDA 008372. CMS demanded that Mallinckrodt immediately correct this error and pay the proper additional rebates for Acthar.

126. According to the first amended complaint filed by relator Landolt in the *Landolt* litigation (the "*Landolt* Complaint"), ever since Mallinckrodt acquired Acthar in August 2014 it has "knowingly paid the [MDRP] less than it owes in rebates for Acthar and instead retained and used for its benefit funds that belong to the Government."

127. Landolt was Mallinckrodt's former Director of Internal Controls, Gross to New Accounting, and Government Reporting until his resignation from the Company in early July 2017. Landolt reported directly to defendant Schaefer.

128. According to the *Landolt* Complaint, after Forshee received the April 2016 letter from CMS, defendant Schaefer directed that the scope of Mallinckrodt's rebate liability should be calculated. Landolt's understanding was that this calculation stood at over $200 million at that time.

129. According to the United States' Complaint in Intervention filed in *Landolt* on March 3, 2020 (the "*Landolt* Government Complaint"), which was supported by numerous documents and emails appended as exhibits, on April 19, 2016, Daley, formerly an analyst in Mallinckrodt's government reporting group, sent Forshee a spreadsheet by email that showed that reverting back to the 1990 base date AMP would result in a 223% increase in the rebate Mallinckrodt owed on Acthar for the first quarter of 2016. Daley indicated to Forshee that this information should be shared with Landolt and defendant Schaefer "to give them an idea of the possible impact."

130. According to the *Landolt* Government Complaint, on April 21, 2016, Daley forwarded Forshee an email chain reflecting that Patty Taylor, a manager in Mallinckrodt's Finance group, and Kevin Healy, a senior director in Mallinckrodt's Regulatory Affairs department, agreed that the correct NDA for purposes of the base date AMP was the 1990 date and not the temporary Type 6 NDA

assigned for the sNDA.

131. According to the *Landolt* Government Complaint, in providing sworn testimony to the government about the April 21, 2016 email, Daley testified that "[Mallinckrodt's r]egulatory [department] agreed with CMS basically."

132. According to the *Landolt* Government Complaint, in providing sworn testimony to the government about the April 21, 2016 email, Forshee agreed with Daley. Specifically, in her sworn testimony, Forshee testified as follows:

> Yes. Yes. If -- if the regulatory department said the new NDA application is going to go away and be rolled into the old one, then that is kind of inconsistent with what we were communicating to CMS saying, oh, we do have a NDA, and we need a new NDC number, you know. [D]efinite[] inconsistency in how Mallinckrodt was treating the NDA and the base AMPs."

133. According to the *Landolt* Government Complaint and the CMS Complaint, on June 2, 2016, CMS sent an email to Forshee, copying Landolt (among others), reiterating that the Company must use the 1990 base date AMP for Acthar, not the later base date AMP that was currently being used, because there was no basis for reporting a 2013 base date AMP for Acthar.

134. According to the *Landolt* Government Complaint, Forshee testified that this email meant that CMS was "requesting that we change the baseline AMP to the original baseline AMP."

135. According to the *Landolt* Government Complaint, on or about June 3, 2016, Forshee, Landolt, defendant Schaefer, and others held a meeting to discuss "CMS Notification – Acthar Baseline AMP."

136. According to the *Landolt* Government Complaint, on June 16, 2016, Forshee sent Landolt and others a detailed spreadsheet showing that, as of June 2016, Mallinckrodt owed $258 million in retroactive rebates.

137. According to the *Landolt* Government Complaint, Forshee testified that she shared this analysis with defendant Schaefer, and that, "[i]f I recall, everyone's reaction was ***it was significantly***

material, the dollar amount." (emphasis added).

138. According to the *Landolt* Complaint, Mallinckrodt further updated its estimated liability in June 2016 for the period ending with the first quarter of 2016 and found that Mallinckrodt owed approximately $265 million in rebates.

139. According to the CMS Complaint and the *Landolt* Government Complaint, on March 20, 2017, CMS emailed Forshee, Landolt, and others at Mallinckrodt to reiterate again that Mallinckrodt needed to revert to the proper base date AMP for Acthar. Specifically, CMS stated, in pertinent part, as follows:

> FDA has confirmed that NDA 022432, a type-6 NDA, was created for administrative purposes because an FDA division other than the division responsible for NDA 008372 was reviewing the application for the new indication. FDA has informed us that type-6 NDAs are administratively closed upon approval. Therefore, ***it is our understanding that the marketing of the drug has always been under the auspices of NDA 008372, regardless of the administratively assigned NDA 022432, which was only for the purpose of FDA approval of the new indication, but not for the approval and marketing of the drug itself.***
>
> The baseline information for a drug that was approved prior to the effective date of section 1927 of the Social Security Act is established using the data of the drug as of 9/30/1990. It is our understanding that NDA 008372 for Acthar was approved on April 29, 1952, ***therefore, the baseline data for the drug that is marketed under that NDA would be based on data from 9/30/1990 as the approval of NDA 022432 in 2010 was not for approval of a new drug.***

(emphasis added).

140. According to the *Landolt* Complaint, Landolt spoke with defendant Schaefer in the spring of 2017 "to express concerns that Mallinckrodt was not responding appropriately to CMS."

141. According to the *Landolt* Complaint, Landolt resigned and left Mallinckrodt in early July 2017.

142. According to the *Landolt* Government Complaint, on March 16, 2018, Lynn Buhl, a director with KPMG LLP, prepared a presentation for defendant Schaefer to present to the Audit Committee (the "March 2018 Audit Committee Presentation"). The March 2018 Audit Committee

Presentation states that CMS informed the Company that "Acthar had to revert to the Base AMP established in 1990" and that complying with this directive would result in "liability [that] would be retroactive to 2010 through current, and ***would be in the hundreds of millions of dollars***." (emphasis added).

143. According to the *Landolt* Government Complaint, the language quoted in ¶142 from the March 2018 Audit Committee Presentation "appeared in several iterations of similar [Mallinckrodt] presentations throughout the remainder of 2018."

144. According to Mallinckrodt's Form DEF14A that was filed with the SEC on April 3, 2019 (the "4/3/19 Form DEF14A"), the Audit Committee met thirteen times during FY18, more than any other Board committee. The 4/3/19 Form DEF14A further explained that the Audit Committee's role was to, among other things, "monitor[] the integrity of our financial statements" and "[Mallinckrodt's] compliance with certain legal and regulatory requirements and the effectiveness of our internal controls."

145. On September 20, 2018, Landolt filed the initial qui tam complaint in *Landolt* under seal, asserting False Claims Act claims against Mallinckrodt for knowingly failing to use the correct base date AMP for Acthar and underpaying hundreds of millions of dollars to the government.

146. According to the CMS Complaint and the *Landolt* Government Complaint, on November 6, 2018, CMS sent a letter by email to, among others, defendant Schaefer, informing the Company that its continued failure to use the correct base date AMP for Acthar would result in, among other things, disallowing Acthar from participating in the MDRP and possibly referring the Company to the DOJ. The letter stated, in pertinent part, as follows:

> On April 13, 2016 and March 20, 2017 CMS informed Mallinckrodt LLC that it was reporting incorrect base [AMP] information and an incorrect FDA application number in the Drug Data Reporting for Medicaid (DDR) system. This is a notice that Mallinckrodt LLC has not taken action to date to correct this information and must do so within 30 days of receiving this notice and notify CMS of its action, otherwise CMS

> will identify the following national drug code (NDC) as "out of compliance" in the DDR system as of December 17, 2018. When an NDC is identified as out of compliance, the submission of pricing records or updates to product data will not be allowed online or via file transfer . . . CMS may also consider referring Mallinckrodt LLC to the Department of Justice . . . as appropriate.

147. On November 12, 2018, Mallinckrodt sent a response to the CMS, copying, among others, defendant Schaefer and Michele Robertson ("Robertson"), Mallinckrodt's current Chief Compliance Officer. According to the 2017 Form 10-K, Robertson reported directly to defendant Trudeau and the Board's Compliance Committee.

148. According to the CMS Complaint, on November 30, 2018, Mallinckrodt's outside counsel scheduled an in-person meeting on January 22, 2019 for Robertson and defendant Casey, among others, to meet with CMS at CMS's offices to discuss the base date AMP for Acthar.

149. According to the *Landolt* Government Complaint, by January 18, 2019, the DOJ had received the *Landolt* initial complaint and sent Mallinckrodt a Civil Investigative Demand ("CID") for documents concerning Acthar's base date AMP.

150. According to the CMS Complaint, on March 7, 2019, Mallinckrodt had another in-person meeting with CMS regarding Acthar's base date AMP that was attended by, among others, defendant Schaefer.

151. According to the *Landolt* Government Complaint, on March 12, 2019, CMS sent a letter to defendant Schaefer to reiterate the points made by CMS during the March 7 meeting, stating, in pertinent part, as follows:

> ***As we have said in our prior communications of April 13, 2016, June 2, 2016, and March 20, 2017, and as we reiterated at the March 7th meeting, the base date AMP of H.P. Acthar Gel should reflect the base date AMP for the drug that was first produced or distributed under new drug application (NDA) 008372***. Because H.P. Acthar gel is currently, and always has been, produced or distributed under NDA 008372, the base date AMP Mallinckrodt is reporting to the Drug Data Reporting for Medicaid (DDR) system does not reflect the appropriate base date AMP, and ***Mallinckrodt has been underpaying Medicaid rebates for H.P. Acthar Gel.***

> We are enclosing a template for you to complete and return to ruth.blatt@cms.hhs.gov in order for Mallinckrodt to report the correct baseline information to the Medicaid Drug Rebate Program.

(emphasis added).

152. According to the CMS Complaint, on March 27, 2019, CMS emailed, among others, defendant Casey to reiterate to Mallinckrodt that the April 13, 2016 letter from CMS to Forshee constituted CMS's final decision on the appropriate base date AMP to use for Acthar.

153. According to the *Landolt* Government Complaint, on April 12, 2019, defendant Casey "wrote to CMS offering to change Acthar's Base Date AMP back to 1990 on a prospective basis only. As consideration for this offer, Mallinckrodt sought an acknowledgment from CMS that 'Mallinckrodt's use of Acthar's post-2012 base date AMP was appropriate.' CMS declined this proposal."

154. According to the *Landolt* Government Complaint, "[t]o date, Mallinckrodt has not corrected its reporting of Acthar's Base Date AMP, and the company continues to pay Medicaid rebates on Acthar without any consideration for the extraordinary increases in the drug's price prior to 2013."

155. On May 10, 2019, CMS sent a letter to defendant Schaefer reiterating the points made in CMS's November 6, 2018 letter, including, among other things, that the base date AMP for Acthar was incorrect and must be reverted to the 1990 base date AMP or else Acthar would be listed as out of compliance and the matter would possibly be referred to the DOJ.

156. Rather than comply with CMS's repeated requests to use the proper base date AMP for Acthar and repay the additional rebates owed to the government, Mallinckrodt took an extraordinary step on May 20, 2019, of suing CMS in the CMS Litigation for preliminary and permanent injunctive relief to stop CMS from reverting the base date AMP of Acthar back to its original 1990 AMP.

157. The CMS Complaint admits that reverting the base date AMP of Acthar would mean that Mallinckrodt would owe the government over $600 million in retroactive additional rebates and

that prospective additional rebate increases going forward would decrease Acthar net sales by approximately 10%.

158. On May 21, 2019, Mallinckrodt announced the CMS Litigation on Form 8-K shortly before the opening of trading, disclosing to investors for the first time that Mallinckrodt owed hundreds of millions of dollars to the government for intentionally using the wrong base date AMP for Acthar. In response to the Company's announcement before the opening of trading on May 21, the price of Mallinckrodt common stock declined approximately $3.80 per share, or 29.1%, from a close of $13.03 per share before the announcement, to close at $9.23 per share on May 22, 2019.

159. Analysts responded to news of the CMS Litigation with shock and surprise. For example, according to a May 21, 2019 J.P. Morgan analyst report, "[t]oday's news obviously represents a meaningful set-back for MNK and continues to highlight controversies surrounding Acthar given legacy price increases on the product . . . CMS has been challenging the company on this for years[.]" J.P. Morgan further stated in a May 24, 2019 analyst report that "[w]e believe that the company will need to demonstrate signs of Acthar stabilization (unlikely now given CMS rebate dispute) . . . to support upside for shares."

160. In addition, according to a May 21, 2019 Wells Fargo analyst report, "[t]he subject of Medicaid risk did not come up when we had the company on the road two weeks ago."

161. Likewise, Piper Jaffray noted in a May 30, 2019 analyst report that "[o]ur bullish thesis had been predicated on the idea of relative sustainability for Acthar . . . . Last week's developments regarding Acthar in the Medicaid setting, along with as much as a $600M CMS-related liability, essentially blew that thesis to smithereens."

162. Following motions for summary judgment by Mallinckrodt and CMS in the CMS Litigation, an oral argument was held on August 2, 2019. During the argument, counsel for CMS stated that "***CMS has spent three-plus years explaining to Mallinckrodt why it needs to comply with the***

statute and Mallinckrodt has refused to do so" and "***CMS was very clear every time they dealt with Mallinckrodt what Mallinckrodt should be doing***." (emphasis added).

163. On March 2, 2020, the United States filed a notice of election to intervene in *Landolt*. That same day, the *Landolt* Complaint was filed and portions of the docket in *Landolt* were publicly unsealed for the first time.

164. On March 3, 2020, the United States filed the *Landolt* Government Complaint, supported by thirty four exhibits that corroborate the allegations contained therein.

165. The DOJ announced the filing of the *Landolt* Government Complaint in a press release on March 3, 2020 that was issued during the trading day (the "3/3/20 Press Release"). The 3/3/20 Press Release was the first time investors learned that Mallinckrodt's failure to use the correct base date AMP for Acthar had exposed the Company to potential False Claims Act liability from a whistleblower and the government. Subsequent news articles that day also revealed to investors for the first time the existence of the *Landolt* litigation. In response to the 3/3/20 Press Release and related news articles, the price of Mallinckrodt common stock declined approximately $1.07 per share, or 25.5%, from an opening price of $4.20 per share before the announcement, to close at $3.13 per share on March 3, 2020.

166. On March 13, 2020, Judge Hogan of the U.S. District Court for the District of Columbia denied Mallinckrodt's motion for a preliminary injunction and granted CMS's motion for summary judgment in the CMS Litigation. According to Judge Hogan's Memorandum Opinion, "Mallinckrodt and Questcor cannot avoid application of the base date AMP that attached when Acthar was approved by the FDA under NDA number 008372 by manufacturing the existence of a distinct 'single source drug' ***through their own self-interested actions in continuing to use NDA number 022432 despite the FDA's direction otherwise***[.]" (emphasis added).

167. Judge Hogan further held that "contrary to Mallinckrodt's insistence that CMS unfairly

and unlawfully changed its position, the record demonstrates that simply was not so." (emphasis added). Judge Hogan also held that Mallinckrodt was fully on notice of CMS's position by 2016, stating that "[f]rom 2016 through 2019, CMS gave [Mallinckrodt] more than ample opportunity to bring its reporting into compliance so it would not continue to accrue rebate underpayments for which it would be liable." (emphasis added).

168. In a press release issued by Mallinckrodt on March 16, 2020 before the opening of trading on Form 8-K (the "3/16/20 Form 8-K"), the Company acknowledged that:

> In the absence of court intervention and based on the effective date of the ruling and change to the base date AMP, ***the company will pay roughly $650 million for the period from January 1, 2013 to present, and this will be reflected as a non-GAAP adjustment in the first quarter results. Based on current Medicaid patient volume, Mallinckrodt estimates the annualized prospective change to the Medicaid rebate calculation will reduce Acthar Gel net sales by roughly $90 million to $100 million [per year].***

(emphasis added).

169. In response to the 3/16/20 Form 8-K, which is the first time that investors learned that Mallinckrodt's effort to avoid paying the hundreds of millions of dollars in rebates owed to CMS lacked any legal basis, the price of Mallinckrodt common stock declined approximately $1.96 per share, or 64.4%, from a close of $3.04 per share before the announcement on March 13, 2020, to close at $1.08 per share on March 18, 2020.

170. Also, on March 16, 2020, Mallinckrodt filed an emergency motion for reconsideration of Judge Hogan's grant of summary judgment in favor of CMS in the CMS Litigation.

171. On May 29, 2020, Judge Hogan denied Mallinckrodt's motion for reconsideration. In the same order, Judge Hogan declined to grant Mallinckrodt's request to enjoin CMS from taking any enforcement action against Mallinckrodt, including locking the Company out of the MDRP and requiring payment of the $600 million plus in past due rebates, while the Company appeals Judge Hogan's decision. Among other reasons, Judge Hogan denied the injunction request because

Mallinckrodt could not establish a reasonable likelihood of success on appeal.

172. On June 1, 2020, Mallinckrodt instituted the CMS Litigation Appeal.

173. On June 2, 2020, Mallinckrodt filed an emergency motion in the CMS Litigation Appeal for a temporary injunction pending resolution of the appeal to enjoin CMS from taking any enforcement action against the Company while the appeal is ongoing, and to expedite briefing and argument.

174. On June 15, 2020, the DC Circuit denied Mallinckrodt's request for a temporary injunction pending resolution of the appeal.

175. According to a press release issued by Mallinckrodt on June 15, 2020 (the "6/15/20 Press Release"), in light of the DC Circuit's decision to deny the injunction, the Company finally changed the base date AMP for Acthar as CMS had been directing for over four years.

176. The 6/15/20 Press Release explained that "[t]he effect of the change is an immediate recognition of retroactive non-recurring charges (estimated at approximately $650 million through mid-June) and the prospective loss of Acthar Medicaid net sales, which has historically contributed to Acthar Gel net sales of $90 to $100 million annually."

177. The 6/15/20 Press Release further stated that "the cash payments for retroactive Medicaid rebate charges will be processed over time, in accordance with the normal rebate payment schedule, and the company expects the cash outlays will most likely commence in the fourth quarter of 2020."

178. In addition, the 6/15/20 Press Release stated that if Mallinckrodt loses the CMS Litigation Appeal then the Company's global settlement reached in the opioid litigation "could be in jeopardy[.]"

179. Also on June 15, 2020, the DC Circuit granted the Company's request to expedite briefing and argument. Briefing is currently underway in the CMS Litigation Appeal and oral

argument is scheduled for September 24, 2020.

180. On August 4, 2020, Mallinckrodt issued a press release on Form 8-K announcing the Company's financial results for the second fiscal quarter of 2020 (the "8/4/20 Form 8-K"). According to the 8/4/20 Form 8-K, Mallinckrodt took a one-time charge of $534.4 million for the six months ended June 26, 2020, related to the Company's adjustment to the base date AMP for Acthar.

181. According to the 8/4/20 Form 8-K, Acthar net sales for the second fiscal quarter of 2020 were $213.7 million, a 19.8% decrease from the same fiscal quarter of 2019, that was partially drive by "the change in the Medicaid rebate calculation."

182. The 8/4/20 Form 8-K further disclosed that, "[d]ue to pressures from the Acthar Gel Medicaid matter," Mallinckrodt has been exploring "the possibility of a filing for reorganization in bankruptcy under Chapter 11 by Mallinckrodt plc and most of its subsidiaries in the near-term."

183. Accordingly, Defendants knew, or recklessly disregarded, that Mallinckrodt's Class Period financial statements were issued in violation of GAAP because they materially inflated Mallinckrodt's reported net sales by understating the amount of Acthar rebates owed to the government and failed to accurately portray the contingent liabilities owed by the Company for the same reason. Defendants' knowing, or reckless, failure to adequately disclose that the wrong base date AMP was being used for Acthar to avoid hundreds of millions of dollars in rebates also rendered false and misleading, among other statements, several Company risk disclosures pertaining to Acthar, and separately violated SEC Items 103, 303, and 503.

Defendants Lacked A Reasonable Basis to Provide the Acthar FY19 Guidance

184. On November 6, 2018, Mallinckrodt reported its financial results for the third fiscal quarter of 2018 ("3Q18") in a press release on Form 8-K. In connection with presenting the Company's 3Q18 financial results, Mallinckrodt held an investor earnings call that same day (the "11/6/18 Conference"). During the 11/6/18 Conference, defendant Trudeau provided net sales

guidance for Acthar for fiscal year 2019 ("FY19"), stating that "we did indicate obviously this morning that we would see Acthar 2019 net sales again being in excess of $1 billion." (the "Acthar FY19 Guidance").

185. Throughout the Class Period, Defendants repeatedly reaffirmed the Acthar FY19 Guidance, including on May 7, 2019, at the Company's investor earnings call in connection with Mallinckrodt's financial results for the first fiscal quarter of 2019 ("1Q19") (the "5/7/19 Conference").

186. The Acthar FY19 Guidance was based, in part, on the Company presenting its financial results in conformance with GAAP.

187. On May 21, 2019, in connection with announcing the CMS Litigation, Mallinckrodt issued a set of questions and answers to investors regarding the litigation. In response to the question "[w]hat is the impact to 2019 financial guidance as a result of CMS decision?[,]" Mallinckrodt again reaffirmed the Acthar FY19 Guidance without a reasonable basis, stating, in pertinent part, that "Mallinckrodt believes changing [the Acthar FY19 G]uidance or taking a reserve is inappropriate at this time."

188. Defendants did not have a reasonable basis to reaffirm the Acthar FY19 Guidance because Mallinckrodt knew, or recklessly disregarded, that Mallinckrodt was illegally using the incorrect base date AMP for Acthar and that CMS's efforts to get Mallinckrodt to comply with its responsibility under the MDRP would cause Acthar's FY19 net sales to decline by approximately 10% and prevent them from equaling or exceeding $1 billion.

189. On August 6, 2019, before the opening of trading, Mallinckrodt reported its financial results for the second fiscal quarter of 2019 ("2Q19") in a press release on Form 8-K (the "8/6/19 Form 8-K"). The 8/6/19 Form 8-K disclosed that "[g]iven current significant market uncertainties, the company now believes Acthar Gel net sales for 2019 are unlikely to exceed $1 billion." On the accompanying investor earnings call held that same day, defendant Trudeau cited the "uncertainty

around CMS reimbursement and Medicaid" as a primary reason why "we expect Acthar results to be weaker in the second half of the year and full year sales are unlikely to exceed $1 billion."

190. In response to the Company's announcement before the opening of trading on August 6, 2019, the price of Mallinckrodt common stock declined $0.84 per share, or approximately 12.9%, from a close of $6.48 per share before the announcement, to close at $5.64 on August 7, 2019.

191. For the remainder of the Class Period, Mallinckrodt declined to provide fiscal year 2020 guidance for Acthar net sales because, as defendant Trudeau stated during an investor earnings call on November 5, 2019, "we're anticipating that we're going to have some pressure on sales due to the CMS situation[.]"

Mallinckrodt Sought to Obtain Additional Indications for Acthar Because of the AMP Base Date Liability

192. During the Class Period, Defendants repeatedly touted the Company's efforts to obtain new clinical trial data as critical to the future success of Acthar. Mallinckrodt had initiated, or had ongoing, numerous clinical trials testing Acthar's utility in treating a variety of conditions during the Class Period, including for: (i) amyotrophic lateral sclerosis ("ALS"), which was not a condition Acthar has previously received FDA approval to treat; (ii) focal segmental glomerular sclerosis; (iii) pulmonary sarcoidosis; (iv) systemic lupus erythematosus; and (v) uveitis.

193. With respect to the ALS trial, on July 16, 2019, Mallinckrodt issued a press release announcing that the trial had been permanently halted because of adverse events experienced by participants in the trial.

194. Defendants repeatedly discussed Acthar's clinical trials during the Class Period, but failed to disclose that one reason why Mallinckrodt pursued them was the significant CMS liability that the Company faced. Specifically, because using the correct base date AMP for Acthar would cause the Company to owe the government hundreds of millions of dollars and Acthar's yearly net sales going

forward to decline by approximately 10%, Mallinckrodt was desperate to find ways to make it appear that alternate revenue opportunities for Acthar existed.

Defendants Knew, or Recklessly Disregarded, When the 2018 Form 10-K Was Issued That Mallinckrodt Faced Significant Liability For Illegally Marketing Acthar

195. In September 2010, Questcor hired Lisa Pratta ("Pratta") as an Acthar neurology specialist, meaning Pratta promoted Acthar to neurologists for MS relapses, optic neuritis, and neuromuscular indications such as dermatomyositis and polymyositis. Pratta worked for Questcor in the New Jersey region. Pratta continued in the same role with Mallinckrodt following the Company's acquisition of Questcor in August 2014.

196. On January 20, 2012, Charles Strunck ("Strunck"), a former Questcor employee, filed the *Strunck* whistleblower litigation, alleging that Questcor violated the False Claims Act by illegally marketing Acthar through kickbacks to doctors and off-label marketing. Pratta later joined the *Strunck* litigation as an additional relator in the fourth amended complaint that was filed in that case on June 13, 2017 (the "*Strunck* Complaint"). The *Strunck* Complaint is sourced by allegations from two relators – Strunck and Pratta.

197. Shortly after she was included in the *Strunck* Complaint, on June 17, 2017, Pratta was fired by Mallinckrodt for complaining about the Company's off-label marketing of Acthar.

198. According to the *Strunck* Complaint, in 2016, Mallinckrodt sponsored a "Reimbursement Advisory Board," in which a sales representative hosted a dinner program for physicians (identified by sales representatives based on their Acthar script writing potential) to teach them how to navigate the prior authorization process, whereby government or private insurers must meet certain requirements in order for them to reimburse Acthar prescriptions. Attendees would be paid $500-$1,000 for their time. These events were elaborate affairs, with doctors being flown to weekend meetings in Orlando or Las Vegas. According to the *Strunck* Complaint, this event

constituted illegal marketing of Acthar.

199. According to the *Strunck* Complaint, in the fall of 2016, Mallinckrodt instructed sales representatives to market and promote Acthar as a "first-line" drug for MS despite the fact that Acthar can only be used for MS after a patient is treated with a different drug and that drug is not successful. There is no scientific literature supporting using Acthar as a first line treatment for MS. Nonetheless, Mallinckrodt VP of Neurology, Kyle Jennings, directed sales representatives to inform physicians that Acthar was indicated as a first line treatment for MS. According to the *Strunck* Complaint, promoting Acthar as a "first-line" drug constituted illegal marketing of Acthar.

200. The 2016 Form 10-K, 2017 Form 10-K, and 2018 Form 10-K contain several statements with respect to Acthar's use as a second-line treatment that are in tension with the allegations in the *Strunck* Complaint. For example, all three Forms 10-K state that "[Acthar] generally is prescribed by physicians when numerous alternative treatments have failed to provide positive outcomes or are not well tolerated by the patient" and "[Acthar] may not be prescribed . . . until alternatives have failed to provide positive patient outcomes[.]"

201. On March 7, 2019, the United States government filed a notice of election to intervene in the *Strunck* litigation.

202. On March 8, 2019, the court presiding over the *Strunck* litigation ordered the *Strunck* Complaint to be unsealed.

203. It was not until *CNN* issued a news story about the *Strunck* litigation on April 30, 2019, that investors learned for the first time about the existence of the *Strunck* Complaint (the "4/30/19 Article"). The 4/30/19 Article describes the *Strunck* Complaint as "newly unsealed documents[.]"

204. Although Mallinckrodt issued its own statement on April 30, 2019, and sought to portray the allegations in the *Strunck* Complaint as pertaining solely to conduct at Questcor, the 4/30/19 Article stated that "the suit makes clear that one of the employees stayed on after the 2014 merger and worked

for Mallinckrodt, leaving the company in June 2017."

205. In response to the 4/30/19 Article, which was publicly released shortly after the market opened on April 30, 2019, the price of Mallinckrodt common stock declined $3.03 per share, or approximately 16.5%, from a close of $18.32 per share before the announcement on April 29, to close at $15.29 on May 1, 2019.

206. Mallinckrodt issued its own press release in response to the *CNN* article on April 30, 2019 (the "4/30/19 Press Release"). The 4/30/19 Press Release made the stunning admission that "[w]hile we are disappointed the DOJ has elected to proceed with the lawsuit, ***we have been in advanced settlement talks with the government over the past several months***." (emphasis added). According to Dictionary.com, the first definition of the word "several" means "being more than two but fewer than many in number or kind." Thus, Mallinckrodt admitted that the Company knew, or recklessly disregarded, the significant legal liability posed by the *Strunck* litigation by at least when the 2018 Form 10-K was issued on February 26, 2019.

207. Likewise, defendant Casey knew, or recklessly disregarded, the significant legal liability posed by the *Strunck* litigation when the March 2019 Proxy Statement, which incorporated the 2018 Form 10-K by reference, was issued.

208. During the Company's next investor earnings call, the 5/7/19 Conference, defendant Trudeau received a question about the *Strunck* litigation and he responded that "our anticipation is that we're likely to be resolving this sooner than later. We'd like to put this behind us."

209. Beyond the significant stock price decline caused by the public revelation of the *Strunck* litigation, analysts believed that the *Strunck* litigation posed a material risk to Mallinckrodt's finances. For example, on May 7, 2019, Wells Fargo stated in an analyst report that "MNK shares have been under pressure over the past week in part due to an Acthar whistleblower complaint. On the call, management indicated that the DOJ intervention related to complaints initially filed in 2012 and 2013

against Questcor. The company has already reserved for an anticipated settlement and hopes to finalize a potential resolution 'that is reasonable and manageable for both parties.'"

210. Likewise, on May 8, 2019, J.P. Morgan stated in an analyst report that "[w]e see an Acthar settlement lifting some of the recent whistleblower headlines on the stock[.]"

211. On September 4, 2019, the DOJ issued a press release announcing that the claims alleged by Strunck and Pratta in the *Strunck* Complaint had been resolved by Mallinckrodt for $15.4 million. Strunck and Pratta split a whistleblower award of $2.926 million.

MATERIALLY FALSE AND MISLEADING STATEMENTS AND OMISSIONS DURING THE CLASS PERIOD

212. During the Class Period, Defendants made materially false and misleading statements, and otherwise violated an obligation to disclose material information, concerning: (i) Mallinckrodt's compliance with GAAP in its financial reporting and financial statements; (ii) Mallinckrodt's provision of the Acthar FY19 Guidance; (iii) Mallinckrodt's failure to disclose the base date AMP liability and information related thereto; (iv) Mallinckrodt's failure to disclose why it was conducting numerous clinical trials for Acthar; and (v) legal proceedings, known uncertainties, and material risks associated with Acthar required to be disclosed under Items 103, 303, and 503.

Mallinckrodt's Financial Reporting During the Class Period Was Materially False and Misleading

213. Generally Accepted Accounting Principles ("GAAP") are the principles recognized by the accounting profession as the conventions, rules, and procedures necessary to define accepted accounting practices at a particular time. Preparing financial statements in compliance with GAAP is a basic fundamental obligation of publicly traded companies.

214. During the Class Period, Mallinckrodt issued to investors, and filed with the SEC, financial statements that violated GAAP and SEC regulations and were, therefore, materially false and misleading.

215. Rule 4-01(a) of SEC Regulation S-X provides that "[f]inancial statements filed with the [SEC] which are not prepared in accordance with generally accepted accounting principles will be presumed to be 'misleading or inaccurate' . . . ." 17 C.F.R. §210.4-01(a)(1). Regulation S-X also requires that interim financial statements filed with the SEC comply with GAAP. 17 C.F.R. §210.10-01(a).

216. Defendants represented that each of the financial statements, and the financial disclosures related thereto, issued by Mallinckrodt during the Class Period on Forms 10-K and 10-Q were presented in conformity with GAAP (the "Class Period Financial Statements").

217. These representations were materially false and misleading when made because the Class Period Financial Statements contained false and misleading representations that masked the illegal scheme to defraud the government of the rebates owed for Acthar perpetrated by Defendants.

218. First, the Company's reported net sales, accrued liabilities and earnings, as well as the disclosures related thereto, provided in the Class Period Financial Statements were materially false and misleading and presented in violation of GAAP. Second, the Class Period Financial Statements failed to disclose the potential fines, penalties and other contingent liabilities ensuing from the unlawful Acthar base date AMP practices perpetrated by Defendants.

219. During the Class Period, Mallinckrodt filed its annual financial statements with the SEC on Form 10-K. The 2016 Form 10-K, 2017 Form 10-K, 2018 Form 10-K, and 2019 Form 10-K each represented, in pertinent part and in all material respects: "[t]he consolidated financial statements have been prepared in U.S. dollars and in accordance with [GAAP]."

220. Similarly, during the Class Period, Mallinckrodt filed its quarterly financial statements with the SEC on Form 10-Q. The 2Q16 Form 10-Q, 3Q16 Form 10-Q, 1Q17 Form 10-Q, 2Q17 Form 10-Q, 3Q17 Form 10-Q, 1Q18 Form 10-Q, 2Q18 Form 10-Q, 3Q18 Form 10-Q, 1Q19 Form 10-Q, 2Q19 Form 10-Q, and 3Q19 Form 10-Q represented, in pertinent part and in all material respects:

"[t]he unaudited condensed consolidated financial statements have been prepared in U.S. Dollars and in accordance with [GAAP]."

221. The representations in the Class Period Financial Statements in ¶¶215-20 above were materially false and misleading when made because, in violation of GAAP, Defendants knowingly or recklessly caused Mallinckrodt to issue the Class Period Financial Statements that: (i) materially inflated Mallinckrodt's reported net sales and understated its reported accrued liabilities, which resulted in concomitant inflation in Mallinckrodt's reported net income; and (ii) misrepresented contingent liabilities associated with the unlawful scheme to avoid Medicaid rebates for Acthar perpetrated by Defendants.

Mallinckrodt's Reported Net Sales, Liabilities, and Earnings Were Materially Misstated

222. Accounting Standards Codification ("ASC") is the source of authoritative GAAP to be applied by nongovernmental entities.

223. ASC Topic 450, *Contingencies*, governs the disclosure and accrual of contingencies. Pursuant to ASC 450-10-20 (Glossary), a "loss contingency" is defined as:

> An existing condition, situation, or set of circumstances involving uncertainty as to possible loss to an entity that will ultimately be resolved when one or more future events occur or fail to occur. The term loss is used for convenience to include many charges against income that are commonly referred to as expenses and others that are commonly referred to as losses.

224. ASC Topic 450-20-25-2 requires the accrual of a loss contingency by a charge against income if: (a) "[i]nformation available before the financial statements are issued or are available to be issued . . . indicates that it is probable [*i.e.*, likely]" a contingent liability or potential loss has been incurred; and (b) "[t]he amount of loss can be reasonably estimated."

225. In its annual financial statements included in the Company's Forms 10-K filed with the SEC during the Class Period, Defendants misleadingly represented that Mallinckrodt's net sales rebates, which include those rebates owed to CMS under the MDRP for Acthar, were accounted for in a

manner consistent with the requirements set forth in GAAP's ASC Topic 450.

226. In the 2016 Form 10-K and the 2017 Form 10-K, Defendants represented, in pertinent part, as follows:

> When we recognize net sales, we simultaneously record an adjustment to revenue for estimated chargebacks, ***rebates***, product returns and other sales deductions. These provisions are estimated based upon historical experience, estimated future trends, estimated customer inventory levels, current contracted sales terms with customers, level of utilization of our products and other competitive factors. We adjust reserves for ***rebates*** and chargebacks, product returns and other sales deductions to reflect differences between estimated and actual experience. Such adjustments impact the amount of sales we recognize in the period of adjustment.

(emphasis added).

227. Similarly, in the 2018 Form 10-K and the 2019 Form 10-K, Defendants represented, in pertinent part, as follows:

> Product sales are recorded at the net sales price (transaction price), which includes estimates of variable consideration for which reserves are established. These reserves result from estimated chargebacks, ***rebates***, product returns and other sales deductions that are offered within contracts between us and our customers, health care providers and payers relating to the sales of our products. These reserves are based on the amounts earned or to be claimed on the related sales and are classified as reductions of accounts receivable (if the amount is payable to the customer) or a current liability (if the amount is payable to a party other than a customer). Where appropriate, these estimates take into consideration a range of possible outcomes which are probability-weighted for relevant factors such as our historical experience, estimated future trends, estimated customer inventory levels, current contracted sales terms with customers, level of utilization of our products and other competitive factors. Overall, these reserves reflect our best estimate of the amount of consideration to which it is entitled based on the terms of the contract.

(emphasis added).

228. Defendants knew, or recklessly disregarded, that the statements in ¶¶226-27 above were materially false and misleading because they omitted to state that Mallinckrodt had materially understated its obligation to issue rebates due the government by fraudulently utilizing the wrong base date AMP for Acthar.

229. When Mallinckrodt intentionally utilized an improper base date AMP for Acthar in

estimating its obligation to pay rebates due the government, it did not adhere to the dictates of its publicly stated policy of accounting for rebates, and GAAP. Because Mallinckrodt did not comply with its publicly stated policy of accounting for rebates, and GAAP, the Class Period Financial Statements contained material misstatements of fact.

230. By utilizing a fraudulent base date AMP for Acthar, Defendants knowingly overstated Mallinckrodt's reported net sales and understated its accrued liabilities by hundreds of millions of dollars during the Class Period, which resulted in a concomitant overstatement of the Company's reported earnings.

231. Defendants knew, or recklessly disregarded, that the Class Period Financial Statements were materially misstated because they were based upon calculations that intentionally understated the Company's obligation to issue rebates due the government by utilizing a fraudulent base date AMP for Acthar. In so doing, Defendants also knew, or recklessly disregarded, that their representations about the Company's operating performance during the Class Period were materially false and misleading.

Mallinckrodt's Contingent Liability Disclosures Were Materially False and Misleading

232. GAAP, in ASC Topic 450, *Contingencies*, also requires that financial statements provide the disclosure of contingent liabilities when there is at least a reasonable possibility [*i.e.*, a greater-than-slight chance] that a loss or an additional loss has been incurred. *See, e.g.*, ASC Topic 450-20-50-3.

233. Defendants, in violation of GAAP, issued the Class Period Financial Statements and failed to disclose contingencies associated with the unlawful scheme to avoid paying CMS the rebates owed for Acthar perpetrated by Defendants.

234. As detailed herein, during the Class Period Defendants engaged in a multi-year conspiracy to illegally cheat the government out of hundreds of millions of dollars in rebates by fraudulently utilizing the wrong base date AMP for Acthar. Because this scheme violated GAAP and was not disclosed in the Class Period Financial Statements, Mallinckrodt was subjected to material

contingent liabilities, including, but not limited to, civil and/or criminal penalties or punishments, including having Acthar excluded from participating in the MDRP.

235. Defendants knew, or recklessly disregarded, that the Class Period Financial Statements were materially misstated because they failed to disclose contingent liabilities required to be disclosed by GAAP that occurred due to Defendants' use of the wrong base date AMP for Acthar to avoid paying hundreds of millions of dollars in rebates owed to CMS.

Mallinckrodt's Base Date AMP Rebate Liability Was Material

236. GAAP, in the SEC's Staff Accounting Bulletin No. 99, Materiality ("SAB No. 99"), provides that materiality in the context of financial information not only includes a quantitative assessment of the magnitude of a misstatement, but also requires a qualitative assessment of the factual context in which the user of the false financial statements would view the financial information.

237. In addition, SAB No. 99 provides that the "volatility of the price of a registrant's securities in response to certain types of disclosures may provide guidance as to whether investors regard quantitatively small misstatements as material."

238. Likewise, GAAP, as articulated in the SEC's Codification of Staff Accounting Bulletins Topic 1M ("CSAB Topic 1M"), provides that materiality in the context of a financial misstatement not only includes an assessment of the magnitude of the misstatement in percentage terms, but also requires an assessment of the factual context in which the user of financial statements would view the financial misstatement (referred to in accounting and auditing literature as "quantitative" and "qualitative" factors).

239. For example, CSAB Topic 1M notes that even quantitatively small financial misstatements may be material if management has intentionally made adjustments to various financial statement items in a manner inconsistent with GAAP. Accordingly, CSAB Topic 1M cautions that SEC registrants "should not assume that even small intentional misstatements in financial statements"

are immaterial.

240. Here, Forshee, Landolt, and defendant Schaefer, among others, understood that the liability posed by Mallinckrodt's failure to use the correct base date AMP for Acthar was "significantly material." The Audit Committee likewise understood the same, being informed by at least March 2018 that the Company owed CMS hundreds of millions of dollars for illegally avoided Acthar rebates.

241. Indeed, the approximate $650 million owed by Mallinckrodt to CMS represents approximately 14.4% of the total amount of Acthar net sales made by Mallinckrodt before and during the Class Period in FY15, FY16, FY17, and FY18 of approximately $4.502 billion.

242. In addition, the approximate 10% reduction in Acthar's net sales on a going forward basis is well above the 5% materiality threshold for assessing quantitative materiality under GAAP. Thus, the liability posed by Mallinckrodt's failure to use the correct base date AMP for Acthar was quantitatively material.

243. This liability was also qualitatively material. When investors first learned about it through the Company's filing of the CMS Complaint on May 21, 2019, Mallinckrodt's stock declined significantly, by approximately 29%. In addition, numerous analysts interpreted this liability to represent a significant threat to Mallinckrodt's financial position, as described above in ¶¶159-61. Likewise, further revelations about the extent of Mallinckrodt's liability to CMS caused the Company's stock price to decline by approximately 25% on March 3, 2020 and approximately 64% on March 16, 2020, respectively, as described above in ¶¶165, 169.

244. Moreover, financial improprieties resulting in financial misstatements of such magnitude bear directly upon the integrity of Mallinckrodt's financial reporting and the risk premium investors assigned to Mallinckrodt's common stock, particularly when such misstatements were associated with improprieties related to the Company's most important drug product. The financial misstatements challenged herein were undoubtedly material to Mallinckrodt's investors.

245. Accordingly, for the reasons above in ¶¶213-44, the financial statements and related financial disclosures contained in the Class Period Financial Statements, which were contained in the Mallinckrodt SEC filings listed below, were materially false and misleading:

Date	Type	Description	Speaker(s)
May 3, 2016	Form 10-Q	Quarterly Report for 2Q16	Mallinckrodt, Trudeau, and Harbaugh
August 2, 2016	Form 10-Q	Quarterly Report for 3Q16	Mallinckrodt, Trudeau, and Harbaugh
November 29, 2016	Form 10-K	Annual Report for FY16	Mallinckrodt, Trudeau, Harbaugh, Schaefer, Booth, Reed, and Russell
May 8, 2017	Form 10-Q	Quarterly Report for 1Q17	Mallinckrodt, Trudeau, and Harbaugh
August 8, 2017	Form 10-Q	Quarterly Report for 2Q17	Mallinckrodt, Trudeau, and Harbaugh
November 7 2017	Form 10-Q	Quarterly Report for 3Q17	Mallinckrodt, Trudeau, and Harbaugh
February 27, 2018	Form 10-K	Annual Report for FY17	Mallinckrodt, Trudeau, Harbaugh, Schaefer, Booth, Reed, and Russell
May 8, 2018	Form 10-Q	Quarterly Report for 1Q18	Mallinckrodt, Trudeau, and Harbaugh
August 7, 2018	Form 10-Q	Quarterly Report for 2Q18	Mallinckrodt, Trudeau, and Harbaugh
November 6, 2018	Form 10-Q	Quarterly Report for 3Q18	Mallinckrodt, Trudeau, and Harbaugh
February 26, 2019	Form 10-K	Annual Report for FY18	Mallinckrodt, Trudeau, Kegler, Schaefer, Reed, Russell, and Carter
March 13, 2019	Form S-8	March 2019 Proxy Statement	Mallinckrodt, Trudeau, Kegler, Schaefer, Reed, Russell, Carter, and Casey
May 7, 2019	Form 10-Q	Quarterly Report for 1Q19	Mallinckrodt, Trudeau, and Reasons
August 6, 2019	Form 10-Q	Quarterly Report for 2Q19	Mallinckrodt, Trudeau, and Reasons

November 5, 2019	Form 10-Q	Quarterly Report for 3Q19	Mallinckrodt, Trudeau, and Reasons
February 26, 2020	Form 10-K	Annual Report for FY19	Mallinckrodt, Trudeau, Kegler, Schaefer, Reed, Russell, and Carter

The Acthar FY19 Guidance Misstatements and Omissions

246. On May 7, 2019, just thirteen days before instituting the CMS Litigation, during the 5/7/19 Conference, defendant Trudeau repeatedly and emphatically assured investors that Mallinckrodt was on track to achieve the Acthar FY19 Guidance. Defendant Trudeau stated, in pertinent part, as follows:

> We continue to expect [Acthar] will be greater than $1 billion in net sales in 2019.
>
> * * *
>
> But the bottom line is we still believe that Acthar is going to be greater than $1 billion in net sales in 2019.
>
> * * *
>
> But importantly, the way to think about 2019 is just like in 2018, this -- we believe this product, again, is going to be in excess of $1 billion. So 2019 is really a transitional year for Acthar. We're going to see some quarter-to-quarter variability, great confidence in the greater than $1 billion and excited about the long-term growth prospects based on the data that we're going to be communicating.
>
> * * *
>
> Again, I think we continue to believe that 2019 is a transitional year for the product. And again, looking at it for a full year, ***I can't emphasize enough that our confidence in greater than $1 billion is consistent.***

(emphasis added).

247. On May 21, 2019, in connection with announcing the CMS Litigation, Acthar issued a set of questions and answers whereupon Mallinckrodt reaffirmed the Acthar FY19 Guidance, stating, in pertinent part, that, notwithstanding the CMS Litigation, "Mallinckrodt believes changing [the Acthar FY19 G]uidance or taking a reserve is inappropriate at this time."

248. The statements referenced above in ¶¶246-47 were materially false and misleading because Defendants misrepresented or failed to disclose the following facts, which were known to or recklessly disregarded by Defendants:

(a) there was no reasonable basis for providing the Acthar FY19 Guidance or reaffirming it because Mallinckrodt was using the incorrect base date AMP for Acthar in order to avoid paying hundreds of millions of dollars in rebates to the government and to avoid having Acthar's net sales be reduced by approximately 10% on a going forward basis;

(b) by virtue of Acthar's net sales being depressed by approximately 10% per year if Mallinckrodt paid the correct rebate for Acthar, this meant that Acthar could not generate net sales in excess of $1 billion in FY19; and

(c) by virtue of these known and/or recklessly disregarded facts, Defendants lacked a reasonable basis for their positive statements about the Company, its earnings, and prospects.

The Acthar Rebate Omissions

249. On May 3, 2016, Defendants filed a Form 10-Q for the fiscal quarter ended March 25, 2016 (the "2Q16 Form 10-Q"), which was signed by defendant Harbaugh, and certified under the Sarbanes-Oxley Act of 2002 ("SOX") by defendants Trudeau and Harbaugh. The 2Q16 Form 10-Q misleading informed investors that the risks associated with investing in Mallinckrodt had not materially changed from when the Company filed its Form 10-K for the year ended September 25, 2015 ("2015 Form 10-K"), which was filed with the SEC on November 24, 2015.

250. The statement in ¶249 was materially false and misleading because it failed to disclose that Mallinckrodt had failed to disclose that the Company was informed by CMS by April 2016 that it owed hundreds of millions of dollars in illegally avoided Acthar rebates to the government.

251. On August 2, 2016, Defendants filed a Form 10-Q for the fiscal quarter ended June 24, 2016 (the "3Q16 Form 10-Q"), which was signed by defendant Harbaugh, and certified under SOX by

defendants Trudeau and Harbaugh. The 3Q16 Form 10-Q misleadingly informed investors that the risks associated with investing in Mallinckrodt had not materially changed from when the Company filed its 2015 Form 10-K.

252. The statement in ¶251 was materially false and misleading because it failed to disclose the material facts set forth in ¶250 above.

253. On November 29, 2016, Mallinckrodt issued the 2016 Form 10-K, which included the Company's financial results and performance for FY16. The 2016 Form 10-K was signed by defendants Trudeau, Harbaugh, Schaefer, Booth, Russell, and Reed. The 2016 Form 10-K misleadingly informed investors that only potential and hypothetical risks existed with respect to Mallinckrodt's obligation to pay rebates to CMS.

254. Specifically, the 2016 Form 10-K stated, in pertinent part, as follows:

> Our reporting and payment obligations under the Medicare and Medicaid rebate programs, and other governmental purchasing and rebate programs, are complex. Any determination of failure to comply with these obligations or those relating to healthcare fraud and abuse laws could have a material adverse effect on our competitive position, business, financial condition, results of operations and cash flows.

255. The statements in ¶254 were materially false and misleading because they failed to disclose that Mallinckrodt had failed to comply with its Medicaid rebate obligations since acquiring Acthar in 2014 and that this failure had resulted in the Company owing hundreds of millions of dollars in illegally avoided rebates to the government.

256. Likewise, the 2016 Form 10-K misleadingly informed investors that "disruption[s]" to Mallinckrodt's ability to generate net sales from Acthar were a risk that could negatively impact the Company's business, stating, in pertinent part, as follows:

> Any disruption in our ability to generate net sales from Acthar could have an adverse impact on our business, financial condition, results of operations and cash flows.

257. The statement in ¶256 was materially false and misleading because it failed to disclose that Mallinckrodt had been informed by April of 2016 by CMS that the Company was using the wrong

base date AMP for Acthar and there was an increased risk of a massive disruption in Mallinckrodt's ability to generate Acthar net sales because using the correct base date AMP for Acthar would result in Acthar's net sales declining by approximately 10% on a yearly basis and the Company was only avoiding this reality by illegally using the wrong base date AMP for Acthar.

258. On May 8, 2017, Defendants filed a Form 10-Q for the fiscal quarter ended March 31, 2017 (the "1Q17 Form 10-Q"), which was signed by defendant Harbaugh, and certified under SOX by defendants Trudeau and Harbaugh.[5] The 1Q17 Form 10-Q provided no update to the Company's risk factors since the filing of the 2017 Form 10-K, stating, in pertinent part, that:

> Item 1A. Risk Factors.
>
> There have been no material changes to the risk factors previously disclosed in Part I, Item 1A. "Risk Factors" in our Annual Report on Form 10-K for the year ended September 30, 2016, filed with the SEC on November 29, 2016.

259. The same statement regarding "no material changes" to Mallinckrodt's risk factors set forth above in ¶258 was repeated in the Company's Form 10-Q for the fiscal quarter ended June 30, 2017 (the "2Q17 Form 10-Q"), filed on August 8, 2017, and in the Company's Form 10-Q for the fiscal quarter ended September 30, 2017 (the "3Q17 Form 10-Q"), filed on November 7, 2017. As with the 1Q17 Form 10-Q, both the 2Q17 Form 10-Q and the 3Q17 Form 10-Q were signed by defendant Harbaugh, and certified under SOX by defendants Trudeau and Harbaugh. This statement in the 1Q17 Form 10-Q, the 2Q17 Form 10-Q, and the 3Q17 Form 10-Q was materially false and misleading when made for failing to disclose the material facts set forth in ¶250 above.

260. On February 27, 2018, the Company issued the 2017 Form 10-K, which included Mallinckrodt's financial results and performance for FY17. The 2017 Form 10-K was signed by defendants Trudeau, Harbaugh, Schaefer, Booth, Russell, and Reed. Like the 2016 Form 10-K, the

[5] In 2016, Mallinckrodt changed the end of its fiscal year from September to December, which is why the dates from 2016 do not match those from 2017-2020 for purposes of the Company's Forms 10-K and 10-Q.

2017 Form 10-K misleadingly informed investors that only potential and hypothetical risks existed with respect to Mallinckrodt's obligation to pay rebates to CMS. Specifically, the 2017 Form 10-K stated, in pertinent part, as follows:

> Our reporting and payment obligations under the Medicare and Medicaid rebate programs, and other governmental purchasing and rebate programs, are complex. Any determination of failure to comply with these obligations or those relating to healthcare fraud and abuse laws could have a material adverse effect on our business.

261. The statements in ¶260 were materially false and misleading because they failed to disclose the material facts set forth in ¶255 above.

262. In addition, the 2017 Form 10-K misleadingly informed investors that Acthar's ability to achieve over $1 billion in net sales in FY17 was "driven by . . . lower rebate expenses."

263. The statement in ¶262 was materially false and misleading because it failed to disclose that Mallinckrodt had achieved "lower rebate expenses" by illegally using an incorrect base date AMP for Acthar that artificially reduced the amount of rebates owed by Mallinckrodt to the government by hundreds of millions of dollars.

264. Likewise, the 2017 Form 10-K again misleadingly informed investors that "disruption[s]" to Mallinckrodt's ability to generate net sales from Acthar were a risk that could negatively impact the Company's business, stating, in pertinent part, as follows:

> Any disruption in our ability to generate net sales from H.P. Acthar Gel could have an adverse impact on our business, financial condition, results of operations and cash flows.

265. The statement in ¶264 was materially false and misleading because it failed to disclose the material facts set forth in ¶257 above.

266. On May 8, 2018, Defendants filed a Form 10-Q for the fiscal quarter ended March 31, 2018 (the "1Q18 Form 10-Q"), which was signed by defendant Harbaugh, and certified under SOX by defendants Trudeau and Harbaugh. The 1Q18 Form 10-Q provided no update to the Company's risk factors since the filing of the 2017 Form 10-K, stating, in pertinent part, that:

> Item 1A. Risk Factors.
>
> There have been no material changes to the risk factors previously disclosed in Part I, Item 1A. "Risk Factors" in our Annual Report on Form 10-K for the year ended December 29, 2017, filed with the SEC on February 27, 2018.

267. The same statement regarding "no material changes" to Mallinckrodt's risk factors set forth above in ¶266 was repeated in the Company's Form 10-Q for the fiscal quarter ended June 30, 2018 (the "2Q18 Form 10-Q"), filed on August 7, 2018, and in the Company's Form 10-Q for the fiscal quarter ended September 30, 2018 (the "3Q18 Form 10-Q"), filed on November 6, 2018. As with the 1Q18 Form 10-Q, both the 2Q18 Form 10-Q and the 3Q18 Form 10-Q were signed by defendant Harbaugh, and certified under SOX by defendants Trudeau and Harbaugh. This statement in the 1Q18 Form 10-Q, the 2Q18 Form 10-Q, and the 3Q18 Form 10-Q was materially false and misleading when made for failing to disclose the material facts set forth in ¶250 above.

268. On February 26, 2019, the Company issued the 2018 Form 10-K, which included Mallinckrodt's financial results and performance for FY18. The 2018 Form 10-K was signed by defendants Trudeau, Kegler, Schaefer, Russell, Carter, and Reed. Like the 2016 and 2017 Forms 10-K, the 2018 Form 10-K misleadingly informed investors that only potential and hypothetical risks existed with respect to Mallinckrodt's obligation to pay rebates to CMS. Specifically, the 2018 Form 10-K stated, in pertinent part, as follows:

> Our reporting and payment obligations under the Medicare and Medicaid rebate programs, and other governmental purchasing and rebate programs, are complex. Any determination of failure to comply with these obligations or those relating to healthcare fraud and abuse laws could have a material adverse effect on our business.

269. The statements in ¶268 were materially false and misleading because they failed to disclose the material facts set forth in ¶255 above.

270. In addition, like the 2016 and 2017 Forms 10-K, the 2018 Form 10-K misleadingly informed investors that "disruption[s]" to Mallinckrodt's ability to generate net sales from Acthar were a risk that could negatively impact the Company's business, stating, in pertinent part, as follows:

> Any disruption in our ability to generate net sales from H.P. Acthar Gel could have an adverse impact on our business, financial condition, results of operations and cash flows.

271. The statement in ¶270 was materially false and misleading because it failed to disclose the material facts set forth in ¶257 above.

272. The 2018 Form 10-K disclosed the existence of the CID sent by the DOJ to Mallinckrodt in January 2019. Instead of accurately disclosing that CMS had repeatedly informed Mallinckrodt for years that it was using the wrong base date AMP for Acthar and that Mallinckrodt owed hundreds of millions of dollars to the government in illegally avoided additional rebates, Mallinckrodt merely disclosed that the CID was served on the Company. Specifically, the 2018 Form 10-K disclosed, in pertinent part, as follows:

> Boston Civil Investigative Demand. In January 2019, the Company received a CID from the U.S. Attorney's Office for the District of Massachusetts for documents related to the Company's participation in the Medicaid Drug Rebate Program. The Company is in the process of responding to this demand for documents, and intends to cooperate with the investigation.

273. The statements in ¶272 were materially false and misleading because they failed to disclose: (i) the true extent of the risk that the CID posed to the Company, including that it was related to an ongoing whistleblower lawsuit that was brought by Mallinckrodt's former head of Internal Controls; (ii) the numerous and unequivocal communications from CMS that Mallinckrodt was using the wrong base date AMP for Acthar; (iii) the hundreds of millions of dollars owed by Mallinckrodt to CMS for illegally avoiding paying additional rebates to CMS; and (iv) the significant cut to Acthar's yearly net sales going forward that would occur once Mallinckrodt began paying the proper rebate.

274. Likewise, the statement in ¶272 that Mallinckrodt "intends to cooperate with the investigation" was materially false and misleading because it failed to disclose that Mallinckrodt had obstructed or ignored CMS's efforts to get the Company to use the correct base date AMP for Acthar for years and that Mallinckrodt was preparing to preemptively sue CMS in order to avoid paying the

rebates it owed under the MDRP.

275. On March 13, 2019, Defendants filed the March 2019 Proxy Statement with the SEC on Form S-8. The March 2019 Proxy Statement was signed by defendants Trudeau, Kegler, Schaefer, Russell, Carter, Reed, and Casey. The March 2019 Proxy Statement incorporated by reference the 2018 Form 10-K, which includes, among other things, the statements, representations, and obligations to comply with Items 103, 303, and 503 therein.

276. The March 2019 Proxy Statement was materially false and misleading because the 2018 Form 10-K, which was incorporated by reference therein, failed to disclose the material facts set forth in ¶¶268-74 above.

277. On May 7, 2019, Defendants filed a Form 10-Q for the fiscal quarter ended March 31, 2019 (the "1Q19 Form 10-Q"), which was signed by defendant Reasons, and certified under SOX by defendants Trudeau and Reasons. The 1Q18 Form 10-Q provided no update to the Company's risk factors since the filing of the 2018 Form 10-K, stating, in pertinent part, that:

> Item 1A. Risk Factors.
>
> There have been no material changes to the risk factors previously disclosed in Part I, Item 1A. "Risk Factors" in our Annual Report on Form 10-K for the year ended December 28, 2018, filed with the SEC on February 26, 2019.

278. The same statement regarding "no material changes" to Mallinckrodt's risk factors set forth above in ¶277 was repeated in the Company's Form 10-Q for the fiscal quarter ended June 30, 2019 (the "2Q19 Form 10-Q"), filed on August 6, 2019, and in the Company's Form 10-Q for the fiscal quarter ended September 30, 2019 (the "3Q19 Form 10-Q"), filed on November 5, 2019. As with the 1Q19 Form 10-Q, both the 2Q19 Form 10-Q and the 3Q19 Form 10-Q were signed by defendant Reasons, and certified under SOX by defendants Trudeau and Reasons. This statement in the 1Q19 Form 10-Q, the 2Q19 Form 10-Q, and the 3Q19 Form 10-Q was materially false and misleading when made for failing to disclose the material facts set forth in ¶250 above.

279. Like the 2018 Form 10-K, the 1Q19 Form 10-Q disclosed the existence of the CID sent by the DOJ to Mallinckrodt in January 2019. Even though the 1Q19 Form 10-Q was filed only thirteen days before the CMS Litigation was instituted by Mallinckrodt, the 1Q19 Form 10-Q also failed to explain that CMS had repeatedly informed Mallinckrodt for years that it was using the wrong base date AMP for Acthar and that Mallinckrodt owed hundreds of millions of dollars to the government in illegally avoided additional rebates. Specifically, the 1Q19 Form 10-Q disclosed, in pertinent part, as follows:

> Boston Civil Investigative Demand. In January 2019, the Company received a CID from the U.S. Attorney's Office for the District of Massachusetts for documents related to the Company's participation in the Medicaid Drug Rebate Program. The Company is in the process of responding to this demand for documents, and intends to cooperate with the investigation.

280. The statements in ¶279 were materially false and misleading because they failed to disclose the material facts set forth in ¶273 above. In addition, the statements in ¶279 were materially false and misleading because they inaccurately stated that Mallinckrodt intended to cooperate with this investigation when, in fact, the Company was preparing to sue CMS in thirteen days to obtain a permanent injunction to shut down this investigation.

281. Further, the 2Q19 Form 10-Q and the 3Q19 Form 10-Q disclosed the same information regarding the CID as the 1Q19 Form 10-Q, again stating, in pertinent part, that Mallinckrodt "intends to cooperate with the investigation" and "is cooperating with the investigation," respectively.

282. The statements in ¶281 were materially false and misleading because they failed to disclose the material facts set forth in ¶274 above.

The Acthar Clinical Trial Omissions

283. The 2016 Form 10-K explains that, after acquiring Acthar from Questcor, Mallinckrodt focused on obtaining clinical trial data for Acthar in an effort to expand Acthar's net sales. The 2016 Form 10-K stated, in pertinent part, as follows:

> ***We have initiated Phase 4 clinical trials to supplement the non-clinical evidence supporting the use of Acthar*** in the treatment of the on-label indications of idiopathic membranous nephropathy and systemic lupus erythematosus. The completion of such ongoing or future clinical trials to provide further evidence on the efficacy of Acthar in the treatment of its approved indications could take several years to complete and will require the expenditure of significant time and financial and management resources. Such clinical trials may not result in data that supports the use of Acthar to treat any of its approved indications. In addition, a clinical trial to evaluate the use of Acthar to treat indications not on the current Acthar label may not provide a basis to pursue adding such indications to the current Acthar label.

284. The statement in ¶283 that "we have initiated Phase 4 clinical trials to supplement the non-clinical evidence supporting the use of Acthar . . . " was materially false and misleading because it failed to disclose that Mallinckrodt sought additional clinical trial data to make it appear that alternative revenue opportunities for Acthar existed to offset the expected 10% decline in net sales as a result of the increased rebates Mallinckrodt now had to pay.

285. The 2017 Form 10-K also explains that, after acquiring Acthar from Questcor, Mallinckrodt focused on obtaining clinical trial data for Acthar in an effort to expand Acthar's net sales. The 2017 Form 10-K stated, in pertinent part, as follows:

> Since acquiring H.P. Acthar Gel, we have initiated critical controlled trials in an effort to expand the product's evidence base and strengthen its clinical profile. For example, we are currently enrolling patients in a Phase 2 study to evaluate H.P. Acthar Gel for patients with Amyotrophic Lateral Sclerosis ("ALS") a progressive and fatal neurodegenerative disorder. In addition, we continue our efforts to extend the value of the product through Phase 4 studies and product enhancements.

286. The statement in ¶285 that "we have initiated critical controlled trials in an effort to expand [Acthar's] evidence base and strengthen its clinical profile" was materially false and misleading because it failed to disclose the material facts set forth in ¶284 above.

287. On August 7, 2018, in connection with presenting Mallinckrodt's financial results for the second fiscal quarter of 2018 ("2Q18"), the Company held an investor earnings call (the "8/7/18 Conference"). During the 8/7/18 Conference, defendant Trudeau touted Mallinckrodt's efforts to obtain clinical trial data to support the use of Acthar. Defendant Trudeau stated, in pertinent part, as

follows:

> With regards to discussions with payers, they continue, as they always do. And we've had some very positive dialogue with those payers, certainly about not only current access, but future access. And recognize that those discussions are really tied pretty closely to the emergence of data, and that's why we're very excited about the future of Acthar, ***because of the volume of data and the type of data that we're starting to introduce to the marketplace***. And so this is an environment, though, that continues, as I said earlier, to be highly variable and volatile. And we expect that to be the case for specialty products, including Acthar, going forward.
>
> But overall, as I said, we're pleased with the performance of Acthar. It's performing essentially in line with our expectations internally, and we continue to believe that the product will be -- will result in net sales in 2018 of greater than $1 billion.

288. The statement in ¶287 regarding "the volume of data and the type of data that [Mallinckrodt is] starting to introduce to the marketplace" was materially false and misleading because it failed to disclose the material facts set forth in ¶284 above.

289. The 2018 Form 10-K again explained that, after acquiring Acthar from Questcor, Mallinckrodt has focused on obtaining clinical trial data for Acthar. The 2018 Form 10-K stated, in pertinent part, as follows:

> Since acquiring H.P. Acthar Gel, we have initiated critical placebo-controlled trials in an effort to expand the product's evidence base and strengthen its clinical profile. There are currently eight ongoing Company-sponsored studies for which the areas of focus include focal segmental glomerular sclerosis ("FSGS") (a nephrotic condition), MS, pulmonary sarcoidosis, RA, systemic lupus erythematosus, uveitis, and amyotrophic lateral sclerosis ("ALS"), which is not a currently approved indication.

290. The statement in ¶289 that "we have initiated critical placebo-controlled trials in an effort to expand [Acthar's] evidence base and strengthen its clinical profile" was materially false and misleading because it failed to disclose the material facts set forth in ¶284 above.

291. On February 26, 2019, in connection with presenting Mallinckrodt's financial results for FY18 and issuing the 2018 Form 10-K, the Company held an investor earnings call (the "2/26/19 Conference"). During the 2/26/19 Conference, defendant Trudeau again touted Mallinckrodt's efforts to obtain clinical trial data for Acthar. Defendant Trudeau stated, in pertinent part, as follows:

> So we're, first of all, very pleased with the performance of Acthar. As we've seen over the past several quarters, the product has had a nice trajectory and is stabilizing at this point. What we're most excited about is prospects for future growth for Acthar, which will be driven by the outcome of the data. And as you well know, we're looking at completing a number of key trials over the next 12 to 24 months. In particular, in 2019, we're going to be reporting out on 2 key studies in RA and MS probably towards the second half of this year. And again, depending on the outcome of that data and future data sets and completion of trials, ***we think the long-term prospects for Acthar growth are quite promising***, and we believe that the long-term growth rates or long-term growth will be driven largely by volume, not price.

292. The statement in ¶291 that "we think the long-term prospects for Acthar growth are quite promising" was materially false and misleading because it failed to disclose the material facts set forth in ¶284 above.

293. On May 7, 2019, during the 5/7/19 Conference, defendant Trudeau again touted Mallinckrodt's efforts to obtain clinical trial data for Acthar. Defendant Trudeau stated, in pertinent part, as follows:

> Again, I think we continue to believe that 2019 is a transitional year for [Acthar]. And again, looking at it for a full year, I can't emphasize enough that our confidence in greater than $1 billion is consistent. ***We do anticipate the next couple of quarters are likely to be in the same range of performance that we saw in the first quarter because the Acthar data sets really start playing out here starting in June***. Longer term, we believe that it's not only the RA data, but it's the MS data, the sarcoidosis data, the lupus data, the uveitis data, the 8 clinical trials that we're running. Again, if that data is positive, based on historical precedent, we would anticipate that volume-based growth is likely to follow. Again, we're at a transition point where we're just starting to introduce that data into the market.

294. The statement in ¶293 that "[w]e do anticipate the next couple of quarters are likely to be in the same range of performance that we saw in the first quarter because the Acthar data sets really start playing out here starting in June" was materially false and misleading because it failed to disclose the material facts set forth in ¶284 above.

The *Strunck* Omissions

295. The 2018 Form 10-K disclosed the existence of the DOJ's investigation into the promotional practices used to sell Acthar, but failed to explain that there was a long-running

whistleblower lawsuit into these practices that Mallinckrodt was actively working to settle with the DOJ. These statements also misleadingly portrayed the DOJ's investigation as potentially posing a risk to the Company, when, in fact, the Company was actively trying to settle these claims. Specifically, the 2018 Form 10-K disclosed, in pertinent part, as follows:

> [I]n September 2012, prior to our acquisition of Questcor Pharmaceuticals, Inc. ("Questcor") in August 2014, a subpoena was received from the U.S. Attorney's Office ('USAO") for the Eastern District of Pennsylvania, requesting documents pertaining to an investigation of its promotional practices, and we are fully cooperating with this investigation. If any of our current practices related to the legacy Questcor business are found to be unlawful, we will have to change those practices, which could have a material adverse effect on our business, financial condition and results of operations. Further, if as a result of this investigation we are found to have violated one or more applicable laws, we could be subject to a variety of fines, penalties, and related administrative sanctions, and our business, financial condition, results of operations and cash flows could be materially adversely affected.

296. The statements in ¶295 were materially false and misleading because they failed to disclose: (i) the existence of the *Strunck* litigation; (ii) Mallinckrodt's then-ongoing efforts to resolve the *Strunck* litigation with the DOJ; and (iii) that the *Strunck* Complaint included allegations of illegal promotional practices for Acthar at Mallinckrodt after it acquired Questcor.

Omissions Based on Violations of Items 103, 303 and 503

297. The SEC created specific rules governing the content of disclosures by public companies in their filings with the SEC. As explained herein, Mallinckrodt's Class Period Forms 10-K and Forms 10-Q failed to comply with Items 103, 303, and 503 of Regulation S-K.

Item 103

298. SEC Regulation S-K requires that every Form 10-K and Form 10-Q filing contain a disclosure of "any material pending legal proceedings," including "any such proceedings known to be contemplated by governmental authorities." 17 C.F.R. § 229.103.

299. For any such contemplated proceeding, Item 103 requires the following information to be disclosed:

> Describe briefly any material pending legal proceedings, other than ordinary routine litigation incidental to the business, to which the registrant or any of its subsidiaries is a party or of which any of their property is the subject. Include the name of the court or agency in which the proceedings are pending, the date instituted, the principal parties thereto, a description of the factual basis alleged to underlie the proceeding and the relief sought. Include similar information as to any such proceedings known to be contemplated by governmental authorities.

300. Pursuant to Item 3 of Form 10-K and Item 1 of Form 10-Q, as required by Item 103, Mallinckrodt's Class Period SEC filings were required to disclose the proceedings that Defendants knew CMS was contemplating if Mallinckrodt continued to use the incorrect base date AMP for Acthar and failed to repay the hundreds of millions of dollars in illegally withheld additional rebates.

301. In addition, pursuant to Item 3 of Form 10-K, as required by Item 103, the 2018 Form 10-K was required to disclose the existence of the *Strunck* litigation, the resolution of which the Company was actively negotiating with the DOJ, both because it was a material pending legal proceeding and because the DOJ intended to intervene in the *Strunck* litigation.

Item 303

302. SEC Regulation S-K requires that every Form 10-K and Form 10-Q filing contain a section called "Management's Discussion and Analysis of Financial Condition and Results of Operations" ("MD&A"), drafted in compliance with Item 303 of Regulation S-K, 17 C.F.R. §229.303. The MD&A requirements are intended to provide material historical and prospective textual disclosures that enable investors and others to assess the financial condition and results of operations of a company, with emphasis on that company's prospects for the future.

303. Pursuant to Item 7 of Form 10-K and Item 2 of Form 10-Q, Mallinckrodt's Class Period SEC filings were required to furnish certain information required under Item 303(a)(3) of Regulation S-K including, among other things:

(a) Describe any unusual or infrequent events or transactions or any significant economic changes that materially affected the amount of reported income from continuing operations

and, in each case, indicate the extent to which income was so affected. In addition, describe any other significant components of revenues or expenses that, in the registrant's judgment, should be described in order to understand the registrant's results of operations; and

(b) Describe any known trends or uncertainties that have had or that the registrant reasonably expects will have a material favorable or unfavorable impact on net sales or revenues or income from continuing operations. If the registrant knows of events that will cause a material change in the relationship between costs and revenues (such as known future increases in costs of labor or materials or price increases or inventory adjustments), the change in the relationship shall be disclosed.

304. Regulation S-K also states that "[t]he discussion and analysis [section] shall focus specifically on material events and uncertainties known to management that would cause reported financial information not to be necessarily indicative of future operating results or of future financial condition."

305. The following were known trends, events, or uncertainties that were having, and were reasonably likely to have, a negative impact on the Company's continuing operations and, therefore, were required to be disclosed by Defendants pursuant to Item 303 in Mallinckrodt's Class Period SEC filings on Forms 10-Q and 10-K, including the March 2019 Proxy Statement:

(a) that CMS repeatedly demanded that Mallinckrodt cease illegally using the incorrect base date AMP for Acthar;

(b) that Mallinckrodt illegally used the incorrect base date AMP for Acthar during the Class Period;

(c) that Mallinckrodt's illegal use of the wrong base date AMP for Acthar artificially reduced the amount of rebates owed by Mallinckrodt to the government by hundreds of millions of dollars, amounts that Mallinckrodt owed to the government; and

(d) that using the correct base date AMP for Acthar would result in Acthar's net sales declining by approximately 10% on a yearly basis in perpetuity.

306. The foregoing facts were required to be disclosed pursuant to Item 303 because they were, among other things: (i) "material events and uncertainties known to management that would cause reported financial information not to be necessarily indicative of future operating results or of future financial condition;" (ii) "known trends or uncertainties that have had or that the registrant reasonably expects will have a material favorable or unfavorable impact on net sales or revenues or income from continuing operations;" and (iii) "unusual or infrequent events or transactions or [] significant economic changes that [were] materially affect[ing] the amount of reported income from continuing operations."

Item 503

307. Pursuant to Item 1A of Form 10-K, Mallinckrodt's Class Period Forms 10-K were required to furnish certain information pursuant to Item 503 of Regulation S-K [17 C.F.R. §229.503], including, among other things, a "discussion of the most significant factors that make the [securities] speculative or risky."[6]

308. Pursuant to Item 1A of Form 10-Q, Mallinckrodt's Class Period Forms 10-Q were required to "[s]et forth any material changes from risk factors as previously disclosed" in Mallinckrodt's Class Period Forms 10-K pursuant to Item 503.

309. Defendants failed to comply with Item 503 by failing to adequately disclose risk factors or material changes in risk factors in these SEC filings.

310. Specifically, as required under Item 503, Defendants failed to disclose in Mallinckrodt's Class Period SEC filings on Forms 10-Q and 10-K, including the March 2019 Proxy Statement, the

[6] In May 2019, Item 503 was relocated to Item 105. The 1Q19 Form 10-Q, 2Q19 Form 10-Q, 3Q19 Form 10-Q, and 2019 Form 10-K were all required to comply with Item 105 in the same manner that Mallinckrodt was previously required to comply with Item 503.

following risks, or material changes in risks:

(a) that Mallinckrodt failed to use the correct base date AMP for Acthar during the Class Period;

(b) that Mallinckrodt would be required to pay the government hundreds of millions of dollars because it knowingly used the wrong base date AMP for Acthar to illegally avoid paying additional rebates; and

(c) that using the correct base date AMP for Acthar would result in Acthar's net sales declining by approximately 10% on a yearly basis in perpetuity.

ADDITIONAL SCIENTER ALLEGATIONS

311. As alleged herein, Mallinckrodt and the Individual Defendants acted with scienter in that they knew, or recklessly disregarded, that the public documents and statements issued or disseminated in the name of the Company were materially false and misleading; knew, or recklessly disregarded, that such statements or documents would be issued or disseminated to the investing public; and knowingly, or recklessly, and substantially participated or acquiesced in the issuance or dissemination of such statements or documents as primary violations of the federal securities laws.

312. As set forth elsewhere herein in detail, Defendants, by virtue of their receipt of information reflecting the true facts regarding Mallinckrodt, their control over, and/or receipt and/or modification of Mallinckrodt's allegedly materially misleading statements and/or their associations with the Company which made them privy to confidential proprietary information concerning Mallinckrodt, participated in the fraudulent scheme alleged herein.

313. Defendants knew and/or recklessly disregarded the false and misleading nature of the information which they caused to be disseminated to the investing public. The fraudulent scheme described herein could not have been perpetrated during the Class Period without the knowledge and complicity or, at least, the reckless disregard of the personnel at the highest levels of the Company,

including the Individual Defendants.

314. The Individual Defendants were each executive officers and/or directors of Mallinckrodt during the Class Period. Based on their roles at Mallinckrodt, each of the Individual Defendants would have been involved with, or knowledgeable about, the wrongdoing alleged herein, which centers on Acthar, the most critical source of the Company's net sales during the Class Period. Thus, Acthar is a core operation of the Company, such that Defendants would have had knowledge of material information related to Acthar during the Class Period.

315. At a minimum, Defendants failed to review or check information that they had a duty to monitor, or ignored obvious signs that their statements were materially false and misleading or contained material omissions. Given the nature and extent of the problems at Mallinckrodt, Defendants knew, or recklessly disregarded, the extent and scope of their statements during the Class Period.

316. Likewise, the Individual Defendants, by virtue of their high-level positions with the Company, directly participated in the management of the Company, oversaw the Company as directors on the Board, were directly involved in the day-to-day operations of the Company at the highest levels, and/or were privy to confidential proprietary information concerning the Company and its business, operations, financial statements, and financial condition, as alleged herein. The Individual Defendants had the ultimate authority over and were involved in drafting, producing, reviewing and/or disseminating the false and misleading statements and information alleged herein, were aware, or recklessly disregarded, that the false and misleading statements regarding the Company were being issued, and approved or ratified these statements, in violation of the federal securities laws.

317. The allegations above also establish a strong inference that Mallinckrodt, as an entity, acted with corporate scienter throughout the Class Period because its officers, directors, management, and agents had actual knowledge of the misrepresentations and omissions of material facts set forth herein (for which they had a duty to disclose), or acted with reckless disregard for the truth because

they failed to ascertain and to disclose such facts, even though such facts were available to them. Such material misrepresentations and/or omissions were done knowingly or with recklessness, and without a reasonable basis, for the purpose and effect of concealing Mallinckrodt's true operating condition and present and expected financial performance from investors. By concealing these material facts from investors, Mallinckrodt maintained and/or increased its artificially inflated common stock price throughout the Class Period.

318. As executives and/or directors of Mallinckrodt, the Individual Defendants are all candidates for imputing corporate scienter to Mallinckrodt.

319. In addition, as executives and/or senior managers of Mallinckrodt, Landolt, Forshee, Robertson, and Daley are also candidates for imputing corporate scienter to Mallinckrodt.

LOSS CAUSATION/ECONOMIC LOSS

320. As detailed herein, Defendants engaged in a scheme to deceive the market and a course of conduct that artificially inflated the price of Mallinckrodt's common stock and operated as a fraud or deceit on Class Period purchasers of the Company's common stock. When Defendants' prior misrepresentations and fraudulent conduct were disclosed and became apparent to the market, the trading price of Mallinckrodt's common stock fell precipitously as the artificial inflation was removed.

321. As a result of their purchases of Mallinckrodt common stock during the Class Period, Plaintiff and the other Class members suffered economic loss, *i.e.*, damages, under the federal securities laws. Defendants' false and misleading statements had the intended effect and caused the Company's common stock to trade at artificially inflated levels throughout the Class Period, reaching as high as $36.08 per share on August 23, 2018.

322. On April 30, 2019, during the trading day, the 4/30/19 Article was publicly released and disclosed to investors for the first time the existence of the *Strunck* litigation and that the DOJ had intervened in the litigation.

323. In response to this revelation, the price of Mallinckrodt common stock declined $3.03 per share, or approximately 16.5%, from a close of $18.32 per share before the announcement on April 29, to close at $15.29 on May 1, 2019.

324. On May 21, 2019, before the opening of trading, Mallinckrodt announced on Form 8-K that the Company had filed the CMS Litigation, disclosing for the first time that CMS believed Mallinckrodt owed the government hundreds of millions of dollars in illegally avoided Acthar rebates.

325. In response to this revelation, the price of Mallinckrodt common stock declined approximately $3.80 per share, or 29.1%, from a close of $13.03 per share before the announcement, to close at $9.23 per share on May 22, 2019.

326. On August 6, 2019, before the opening of trading, Mallinckrodt reported its 2Q19 financial results and disclosed, among other things, that the Company would not achieve the Acthar FY19 Guidance.

327. In response to the Company's announcement before the opening of trading on August 6, 2019, the price of Mallinckrodt common stock declined $0.84 per share, or approximately 12.9%, from a close of $6.48 per share before the announcement, to close at $5.64 on August 7, 2019.

328. On March 3, 2020, during the trading day, the DOJ issued the 3/3/20 Press Release and disclosed, among other things, that Mallinckrodt's failure to use the correct base date AMP for Acthar had exposed the Company to False Claims Act liability from a whistleblower and the government in addition to the existing liability owed to CMS.

329. In response to the issuance of the 3/3/20 Press Release during the trading day on March 3, 2020, the price of Mallinckrodt common stock declined approximately $1.07 per share, or 25.5%, from an opening price of $4.20 per share before the announcement, to close at $3.13 per share on March 3, 2020.

330. On March 16, 2020, before the opening of trading, Mallinckrodt issued the 3/16/20

Form 8-K, and disclosed, for the first time, that Mallinckrodt's effort to avoid paying the hundreds of millions of dollars in rebates owed to CMS lacked any legal basis.

331. In response to the Company's announcement before the opening of trading on March 16, 2020, the price of Mallinckrodt common stock declined $1.96 per share, or approximately 64.4%, from a close of $3.04 per share before the announcement, to close at $1.08 per share on March 18, 2020.

332. As shown above, the timing and magnitude of the price declines in Mallinckrodt's common stock negate any inference that the losses suffered by Plaintiff and the Class were caused by changed market conditions, macroeconomic or industry factors, or Company-specific facts unrelated to Defendants' fraud.

CLASS ACTION ALLEGATIONS

333. Plaintiff brings this action as a class action pursuant to Federal Rule of Civil Procedure 23(a) and (b)(3) on behalf of a class consisting of all purchasers of the common stock of Mallinckrodt during the Class Period, inclusive, and who were damaged thereby (the "Proposed Class"). Excluded from the Proposed Class are Defendants, the officers and directors of the Company at all relevant times, members of their immediate families and their legal representatives, heirs, successors or assigns, and any entity in which Defendants have or had a controlling interest.

334. The members of the Proposed Class are so numerous that joinder of all members is impracticable. Throughout the Class Period, Mallinckrodt common stock was actively traded on the NYSE. While the exact number of Proposed Class members is unknown to Plaintiff at this time and can only be ascertained through appropriate discovery, Plaintiff believes that there are hundreds, if not thousands, of members in the Proposed Class. Record owners and other members of the Proposed Class may be identified from records maintained by Mallinckrodt and/or its transfer agent and may be notified of the pendency of this action by mail or by electronic mail, using the form of notice similar to that customarily used in securities class actions.

335. Plaintiff's claims are typical of the claims of the members of the Proposed Class as all members of the Proposed Class are similarly affected by Defendants' wrongful conduct in violation of federal law that is complained of herein.

336. Plaintiff will fairly and adequately protect the interests of the members of the Proposed Class and has retained counsel competent and experienced in class and securities litigation.

337. Common questions of law and fact exist as to all members of the Proposed Class and predominate over any questions solely affecting individual members of the Proposed Class. Among the questions of law and fact common to the Proposed Class are:

(a) whether statements made by Defendants misrepresented material facts about the business, operations, and management of Mallinckrodt;

(b) whether Defendants failed to disclose material facts in discussing the business, operations, and management of Mallinckrodt, making those statements materially false and misleading;

(c) whether the federal securities laws were violated by Defendants' acts or omissions as alleged herein;

(d) whether the price of Mallinckrodt stock was artificially inflated during the Class Period; and

(e) to what extent the members of the Proposed Class have sustained damages and the proper measure of damages.

338. A class action is superior to all other available methods for the fair and efficient adjudication of this controversy since joinder of all members is impracticable. Furthermore, as the damages suffered by individual Class members may be relatively small, the expense and burden of individual litigation make it impossible for members of the Proposed Class to individually redress the wrongs done to them. There will be no difficulty in the management of this action as a class action.

NO SAFE HARBOR

339. The statutory safe harbor provided for forward-looking statements under certain circumstances does not apply to any of the false statements challenged herein. Many of the statements challenged herein were not identified as "forward-looking statements" when made. To the extent there were any forward-looking statements, no meaningful cautionary statements identified important factors that could cause actual results to differ materially from those in the purportedly forward-looking statements. Alternatively, to the extent that the statutory safe harbor does apply to any forward-looking statements pleaded herein, Defendants are liable for those false forward-looking statements because at the time each of those forward-looking statements was made, the particular speaker knew that the particular forward looking statement was false, and/or the forward-looking statement was authorized and/or approved by an executive officer of the Company who knew that those statements were false when made.

APPLICATION OF PRESUMPTION OF RELIANCE:
THE *BASIC* AND *AFFILIATED UTE* PRESUMPTIONS

340. Plaintiff will rely upon the presumption of reliance established by the fraud on the market doctrine as outlined in *Basic Inc. v. Levinson*, 485 U.S. 224 (1988) ("*Basic*") and the presumption of reliance for omissions as outlined in *Affiliated Ute Citizens of Utah v. United States*, 406 U.S. 128 (1972) ("*Affiliated Ute*").

341. With respect to the *Basic* presumption, a presumption of reliance under the fraud on the market doctrine is appropriate because, among other things:

(a) Defendants made public misrepresentations and failed to disclose material facts during the Class Period;

(b) the misrepresentations and omissions were material;

(c) Mallinckrodt's common stock traded in an efficient market;

(d) the misrepresentations and omissions alleged would tend to induce a reasonable investor to misjudge the value of the Company's stock; and

(e) Plaintiff and other members of the Proposed Class purchased Mallinckrodt common stock between the time Defendants misrepresented or failed to disclose material facts and the time the true facts were disclosed, without knowledge of the misrepresented or omitted facts.

342. At all relevant times, the market for Mallinckrodt common stock was efficient for the following reasons, among others:

(a) Mallinckrodt common stock met the requirements for listing and was listed and actively traded on the NYSE, a highly efficient, electronic stock market;

(b) as a regulated issuer, Mallinckrodt filed periodic public reports with the SEC and the NYSE;

(c) Mallinckrodt regularly communicated with public investors via established market communication mechanisms, including regular disseminations of press releases on the national circuits of major newswire services and other wide-ranging public disclosures, such as communications with the financial press and other similar reporting services; and

(d) Mallinckrodt was followed by numerous securities analysts employed by major brokerage firms who wrote reports which were distributed to the sales force and certain customers of their respective brokerage firms. Each of these reports was publicly available and entered the public marketplace.

343. As a result of the foregoing, the market for Mallinckrodt common stock promptly digested current information regarding Mallinckrodt from all publicly available sources and reflected such information in the price of the stock. Under these circumstances, all purchasers of Mallinckrodt common stock during the Class Period suffered similar injury through their purchase of Mallinckrodt common stock at artificially inflated prices and a presumption of reliance applies.

344. In addition to the *Basic* presumption, a class-wide presumption of reliance is also appropriate in this action under the Supreme Court's holding in *Affiliated Ute* because the claims of the Proposed Class are grounded on Defendants' material omissions. Because this action involves Defendants' failure to disclose material adverse information regarding Mallinckrodt's central business operations – information that Defendants were obligated to disclose – positive proof of reliance is not a prerequisite to recovery. All that is necessary is that the facts withheld be material in the sense that a reasonable investor might have considered them important in making investment decisions. Given the importance of the Class Period material misstatements and omissions set forth above, that requirement is satisfied here.

COUNT I

For Violations of §10(b) of the Exchange Act and Rule 10b-5 Against All Defendants

345. Plaintiff repeats and realleges each and every allegation contained above as if fully set forth herein.

346. During the Class Period, Defendants disseminated or approved the materially false and misleading statements specified above, which they knew or deliberately disregarded were misleading in that they contained misrepresentations and/or failed to disclose material facts necessary in order to make the statements made, in light of the circumstances under which they were made, not misleading.

347. Defendants: (i) employed devices, schemes, and artifices to defraud; (ii) made untrue statements of material fact and/or omitted to state material facts necessary to make the statements not misleading; and (iii) engaged in acts, practices, and a course of business which operated as a fraud and deceit upon the purchasers of Mallinckrodt common stock during the Class Period.

348. Plaintiff and the Proposed Class have suffered damages in that, in reliance on the integrity of the market, they paid artificially inflated prices for Mallinckrodt common stock. Plaintiff and the Proposed Class would not have purchased Mallinckrodt common stock at the prices they paid,

or at all, if they had been aware that the market prices had been artificially and falsely inflated by Defendants' misleading statements and/or omissions.

349. As a direct and proximate result of Defendants' wrongful conduct, Plaintiff and the other members of the Proposed Class suffered damages in connection with their purchases of Mallinckrodt common stock during the Class Period.

COUNT II

For Violations of §20(a) of the Exchange Act Against the Individual Defendants

350. Plaintiff repeats and realleges each and every allegation contained above as if fully set forth herein.

351. The Individual Defendants acted as controlling persons of Mallinckrodt within the meaning of Section 20(a) of the Exchange Act as alleged herein. By reason of their positions as officers and/or directors of Mallinckrodt, the Individual Defendants had the power and authority to cause Mallinckrodt to engage in the wrongful conduct complained of herein. By reason of such conduct, the Individual Defendants are liable pursuant to Section 20(a) of the Exchange Act.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff prays for relief and judgment, as follows:

A. Determining that this action is a proper class action, certifying Plaintiff as a Class Representative under Rule 23 of the Federal Rules of Civil Procedure, and appointing Robbins Geller Rudman & Dowd LLP as Class Counsel;

B. Awarding compensatory damages in favor of Plaintiff and the Proposed Class against all Defendants, jointly and severally, for all damages sustained as a result of Defendants' wrongdoing, in an amount to be proven at trial, including interest thereon;

C. Awarding Plaintiff and the Proposed Class their reasonable costs and expenses incurred in this action, including counsel fees and expert fees; and

D. Awarding Plaintiff and the Proposed Class such other and further relief as may be just and proper under the circumstances.

JURY DEMAND

Plaintiff demands a trial by jury.

DATED: August 10, 2020

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